

EXHIBIT 1

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH LLC, WYETH)	
PHARMACEUTICALS LLC, PF PRISM)	
C.V., PBG PUERTO RICO LLC and)	
PF PRISM IMB B.V.)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 16-1305 (RGA)
)	CONSOLIDATED
SUN PHARMACEUTICAL INDUSTRIES)	
LIMITED and SUN PHARMACEUTICAL)	
INDUSTRIES, INC.,)	
)	
Defendants.)	
)	
)	

JOINT STATEMENT OF UNCONTESTED FACTS

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I. PARTIES AND BACKGROUND

A. Plaintiffs (collectively, “Pfizer”)

1. Wyeth LLC is a limited liability company organized and existing under the laws of Delaware and having its principal place of business at 235 East 42nd Street, New York, New York 10017. Pfizer Inc. is the ultimate parent company of Wyeth LLC.

2. Wyeth Pharmaceuticals LLC is a limited liability company organized and existing under the laws of Delaware and having its principal place of business located at 500 Arcola Road, Collegeville, Pennsylvania 19426. Pfizer Inc. is the ultimate parent company of Wyeth Pharmaceuticals LLC.

3. PF PRISM C.V. is a limited partnership (*commanditaire vennootschap*) organized under the laws of the Netherlands, having its registered seat in Rotterdam, the Netherlands, and registered at the Trade Register held by the Chamber of Commerce in Rotterdam, the Netherlands, under number 51840456. Pfizer Inc. is the ultimate parent company of PF PRISM C.V.

4. PBG Puerto Rico LLC is a domestic limited liability company organized and existing under the laws of Puerto Rico with offices at Professional Offices Park V, 996 San Roberto Street, 4th Floor, San Juan, PR 00926. Pfizer Inc. is the ultimate parent company of PBG Puerto Rico LLC.

5. PF PRISM IMB B.V. is a private limited liability company (*besloten vennootschap*) under the laws of the Netherlands, having its registered seat in Rotterdam, the Netherlands, and having its business address at Rivium Westlaan 142, 2909 LD, Capelle aan den IJssel, the Netherlands. Pfizer Inc. is the ultimate parent company of PF PRISM IMB B.V.

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B. Defendants (collectively, “Sun”)

6. Sun Pharmaceutical Industries Limited is a company organized and existing under the laws of India, having its principal place of business at CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai, Maharashtra, India 400063.

7. Sun Pharmaceutical Industries, Inc. is a company organized and existing under the laws of Michigan, having its principal place of business at 1 Commerce Drive, Cranbury, New Jersey 08512.

II. PATENTS-IN-SUIT

A. United States Patent No. 7,417,148 (the “’148 patent”)

8. The ‘148 patent issued on August 26, 2008 and is entitled “4-anilino-3-quinolinecarbonitriles for the treatment of chronic myelogenous leukemia (CML).”

9. The ‘148 patent names Frank Boschelli, Kim T. Arndt, and Jennifer M. Golas as inventors.

10. The ‘148 patent is assigned to Wyeth LLC.

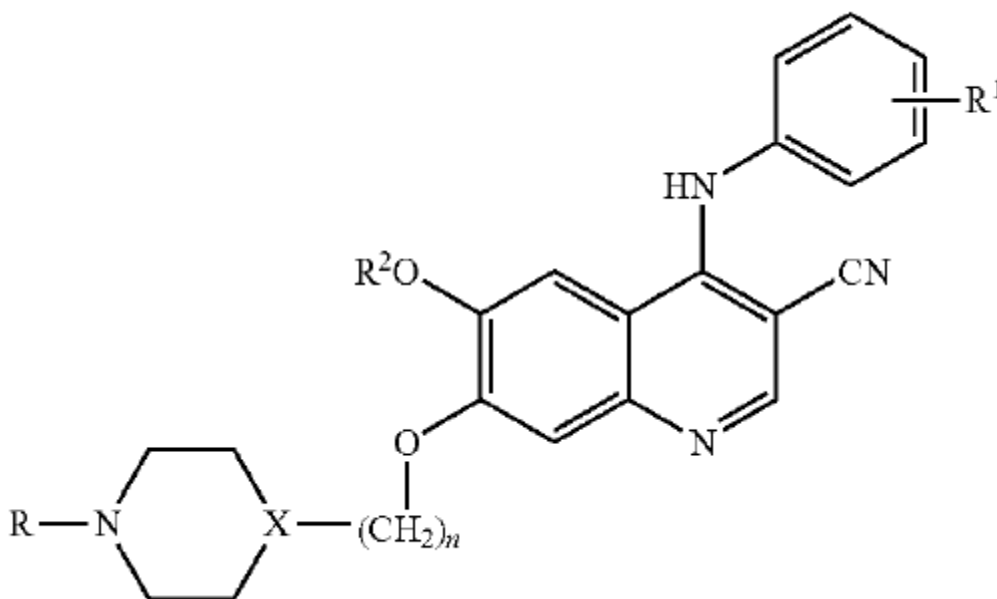
11. The ‘148 patent issued from U.S. Patent Application No.. 60/517,819, filed on November 6, 2003.

12. Claims 1 and 7 of the ‘148 patent are shown below.

13. Pfizer asserts infringement against Sun of claim 7 of the ‘148 patent.

14. Sun asserts at least claim 7 of the ‘148 patent is invalid.

Claim: 1 (not asserted)
1. A method of treating or inhibiting the proliferation of CML comprising, providing to a patient in need thereof a therapeutically effective amount of a compound of the formula:

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wherein:

n is an integer from 1-3;

X is N, CH, provided that when X is N, n is 2 or 3;

R is alkyl of 1 to 3 carbon atoms;

R¹ is 2, 4-diCl, 5-OMe; 2, 4-diCl; 3, 4, 5-tri-OMe; 2-Cl, 5-OMe; 2-Me, 5-OMe; 2, 4-di-Me; 2, 4-diMe-5-OMe, 2, 4-diCl, 5-OEt;

R² is alkyl of 1 to 2 carbon atoms, and pharmaceutically acceptable salts thereof.

Claim 7 (asserted)
<p>7. The method of claim 1 wherein the compound is: 4-[(2,4-Dichloro-5-methoxyphenyl)amino]-6-methoxy-7-[3-(4-methyl-1-piperazinyl)propoxy]-3-quinolinecarbonitrile.</p>

15. The compound specified as “4-[(2,4-Dichloro-5-methoxyphenyl)amino]-6-methoxy-7-[3-(4-methyl-1-piperazinyl)propoxy]-3-quinolinecarbonitrile” in claim 7 of the ‘148 patent is bosutinib.

16. The ‘148 patent is listed in FDA’s “Approved Drug Products with Therapeutic Equivalence Evaluations” (“Orange Book”), with respect to BOSULIF.

EXHIBIT 1**B. United States Patent No. 7,767,678 (the “’678 patent”)**

17. The ’678 patent issued on August 3, 2010 and is entitled “Crystalline forms of 4-[(2,4-dichloro-5-methoxyphenyl)amino]-6-methoxy-7-[3-(4-methyl-1-piperazinyl)propoxy]-3-quinolinecarbonitrile and methods of preparing the same.”

18. The ’678 patent names Marc Sadler Tesconi, Gregg Feigelson, Henry Strong, and Hong Wen as inventors.

19. The assignee of the ’678 patent is listed as Wyeth LLC.

20. The ’678 patent issued from Application No. US11/478,216 (“the ’216 application”), filed on June 29, 2006. The ’216 application claims priority to U.S. Provisional Application No. 60/696,381, filed July 1, 2005.

21. Claims 1, 2 and 3 of the ’678 patent are shown below.

22. Pfizer asserts infringement against Sun of claims 2 and 3 of the ’678 patent.

23. Sun asserts at least claims 2 and 3 of the ’678 patent are invalid.

Claim: 1 (not asserted)
1. An isolated crystalline form of 4-[(2,4-dichloro-5-methoxyphenyl)amino]-6-methoxy-7-[3-(4-methyl-1-piperazinyl)propoxy]-3-quinolinecarbonitrile monohydrate having an x-ray diffraction pattern wherein at least one of the 2 θ angles (°) of the significant peaks are at about: 9.19, 11.48, 14.32, 19.16, 19.45, 20.46, 21.29, 22.33, 23.96, 24.95, 25.29, 25.84, 26.55, 27.61, and 29.51.
Claim: 2 (asserted)
2. The crystalline form of 4-[(2,4-dichloro-5-methoxyphenyl)amino]-6-methoxy-7-[3-(4-methyl-1-piperazinyl)propoxy]-3-quinolinecarbonitrile monohydrate of claim 1, having an x-ray diffraction pattern wherein 2 θ angles (°) of significant peaks are at about: 9.19, 9.98, 11.48, 14.32, 14.85, 15.64, 19.16, 19.45, 19.71, 20.46, 21.29, 22.33, 22.58, 23.96, 24.95, 25.29, 25.84, 26.55, 27.61, 28.42, 29.51, 30.32, 31.40, and 32.39.
Claim: 3 (asserted)
3. The crystalline form of 4-[(2,4-dichloro-5-methoxyphenyl)amino]-6-methoxy-7-[3-(4-methyl-1-piperazinyl)propoxy]-3-quinolinecarbonitrile monohydrate of claim 2, having the x-ray diffraction pattern substantially as shown in FIG. 1 as Pattern A.

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24. The compound specified as “4-[(2,4-dichloro-5-methoxyphenyl)amino]-6-methoxy-7-[3-(4-methyl-1-piperazinyl)propoxy]-3-quinolinecarbonitrile” in claims 1, 2, and 3 of the ’678 patent is bosutinib.

25. The ’678 patent is listed in the Orange Book with respect to BOSULIF.

C. United States Patent No. 7,919,625 (the “’625 patent”)

26. The ’625 patent issued on April 5, 2011 and is entitled “4-anilino-3-quinolinecarbonitriles for the treatment of chronic myelogenous leukemia (CML).”

27. The ’625 patent names Frank Boschelli, Kim T. Arndt, and Jennifer M. Golas as inventors.

28. The assignee of the ’625 patent is listed as Wyeth LLC.

29. The ’625 patent issued from Application No. 12/139,834 (“the ’834 application”), filed on June 16, 2008. The ’834 application is a continuation of the ’097 application, which claims priority to U.S. Provisional Application No. 60/517,819, filed November 6, 2003.

30. Pfizer asserts infringement against Sun of claim 1 of the ’625 patent.

31. Sun asserts claim 1 of the ’625 patent is invalid.

Claim: 1 (asserted)
1. A pharmaceutical composition comprising a CML inhibiting amount of the compound 4-[(2,4-Dichloro-5-methoxyphenyl)amino]-6-methoxy-7-[3-(4-methyl-1-piperazinyl)propoxy]-3-quinolinecarbonitrile.

32. The compound specified in claim 1 of the ’625 patent as “4-[(2,4-Dichloro-5-methoxyphenyl)amino]-6-methoxy-7-[3-(4-methyl-1-piperazinyl)propoxy]-3-quinolinecarbonitrile” is bosutinib.

33. FDA’s Orange Book lists the ’625 patent with respect to BOSULIF.

EXHIBIT 1**III. CLAIM CONSTRUCTION**

34. The parties agreed to the constructions of certain terms as follows. (Joint Claim Construction Br., D.I. 91 at 3-4).

Term	Parties' Agreed Construction
<p>“[a] method of treating or inhibiting the proliferation of CML”</p> <p>Appears in '148 patent claim 1.</p>	<p>The preamble is limiting.</p>
<p>“therapeutically effective amount”</p> <p>Appears in '148 patent claim 1.</p>	<p>“an amount sufficient to cure or ameliorate symptoms of CML”</p>
<p>“4-[(2,4-dichloro-5-methoxyphenyl)amino]-6-methoxy-7-[3-(4-methyl-1-piperazinyl)propoxy]-3-quinolinecarbonitrile”</p> <p>Appears in '678 patent claims 1, 2, 3, 4, and 12.</p>	<p>“bosutinib”</p>
<p>“an x-ray diffraction pattern wherein at least one of the 2θ angles (°) of the significant peaks are at about”</p> <p>Appears in '678 patent claim 1.</p>	<p>“an x-ray diffraction pattern wherein one or more of the 2θ angles of the ‘significant peaks’ are at about”</p>
<p>“therapeutically effective amount”</p> <p>Appears in '678 patent claim 12.</p>	<p>“an amount sufficient to cure or ameliorate symptoms of the disease being treated, such as cancer”</p>

35. The Court held a claim construction hearing and issued a *Markman* Order on June 27, 2018. (*Markman* Order, D.I. 98).

	Term	Court's Construction
A	<p>“crystalline form of [bosutinib] monohydrate”</p> <p>Appears in '678 patent claims 1-4.</p>	<p>a crystalline form of bosutinib containing one molecule of water per molecule of bosutinib wherein the water molecule appears at a regular position within the crystalline lattice</p>

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B	<p>“[a]n isolated crystalline form of [bosutinib] monohydrate”</p> <p>Appears in '678 patent claims 1 and 4.</p>	<p>“isolated” means more than fifty percent of the crystalline bosutinib present is [a particular form]</p>
C	<p>“significant peaks”</p> <p>Appears in '678 patent claims 1-2.</p>	<p>“significant peaks” does not need construction</p>
D	<p>“crystalline form”</p> <p>Appears in '678 patent claims 2-3.</p>	<p>“crystalline form” in Claims 2 and 3 is an “isolated crystalline form”</p>
E	<p>“substantially as shown”</p> <p>Appears in '678 patent claims 3, 12.</p>	<p>“substantially as shown” does not need construction</p>
F	<p>“more than 50% by weight of said therapeutically effective amount consists of a crystalline form having an x-ray diffraction pattern substantially as shown in FIG. 1 as Pattern A and in FIG. 11 as Form I”</p> <p>Appears in '678 patent claim 12.</p>	<p>no further construction is necessary</p>
G	<p>“pharmaceutical composition”</p> <p>Appears in '625 patent claim 1.</p>	<p>“a pharmaceutically acceptable composition containing the specified compound and one or more excipients”</p>

IV. SUN’S PROPOSED ANDA PRODUCT

36. Pursuant to Abbreviated New Drug Application (“ANDA”) No. 209577 Sun seeks to market generic 100 mg and 500 mg bosutinib tablets (“Sun’s ANDA Tablets”) prior to the expiration of the ‘148, ‘625 and ‘678 patents.

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Pursuant to Local Rule 16.3(c)(5), Plaintiffs identify the following issues of law that remain to be litigated, including citations to the authorities upon which Plaintiffs rely. The following statements are not exhaustive, and Plaintiffs reserve the right to prove any matters identified in their pleadings, interrogatory responses, and/or expert reports. Plaintiffs intend to offer evidence as to the issues of fact and issues of law identified in this pretrial order. Plaintiffs also intend to offer evidence to rebut evidence offered by Defendants. Plaintiffs reserve the right to modify or amend this Statement to the extent necessary to reflect any future rulings by the Court and to supplement or amend this Statement to fairly respond to any new issues that Defendants may raise. To the extent that Plaintiffs' Statement of Issues of Fact that Remain to be Litigated, which is submitted as Exhibit 2, contains issues of law, those issues are incorporated herein by reference. Moreover, if any issue of law identified below should properly be considered an issue of fact, then such statement shall be considered to be part of Plaintiffs' Statement of Issues of Fact That Remain to be Litigated. Plaintiffs incorporate by reference their expert reports in support of any proof to be presented by expert testimony.

I. WHETHER PLAINTIFFS HAVE PROVEN BY A PREPONDERANCE OF THE EVIDENCE THAT SUN INFRINGES THE '148, '625, AND '678 PATENTS

A. Background: The Hatch-Waxman Act

1. The Hatch-Waxman Act of 1984 established an expedited process for bringing generic drugs to market. 21 U.S.C. § 355; 35 U.S.C. § 271(e). The statute allows generic drug manufacturers to file less extensive (and less expensive) applications for FDA approval than would otherwise be required. This short form application, known as an Abbreviated New Drug Application (ANDA), relies on the FDA's prior determinations of safety and efficacy in evaluating the branded drug. The generic drug manufacturer need only demonstrate that a

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proposed generic product is “bioequivalent” to the FDA-approved branded product. *See* 21 C.F.R. § 314.54.

2. Patents with claims that cover the approved branded drug or an approved use of the branded drug are listed in the FDA’s “Approved Drug Products With Therapeutic Equivalence Evaluations,” commonly referred to as the Orange Book. When filing an ANDA, a generic drug manufacturer must provide a certification regarding the patent status of any Orange Book-listed patent covering the branded drug. 21 U.S.C. § 355(b)(2)(A). Specifically, the generic drug manufacturer must certify that “in the opinion of the applicant and to the best of his knowledge,” the proposed generic drug does not infringe any patent listed with the FDA as covering the branded drug. *Id.* The generic drug manufacturer can make one of four certifications: (i) that no patent information has been listed in the Orange Book in relation to the branded drug; (ii) that any Orange Book-listed patent has expired; (iii) that the Orange Book-listed patents will expire on a specific date, and the FDA can delay approval of the ANDA until that date; or (iv) that any Orange Book-listed patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug. *Id.* After making the last certification, known as a Paragraph IV certification, the generic drug manufacturer must provide notice to the branded drug manufacturer of the certification and a supporting explanation of the basis for the assertion of invalidity or non-infringement. 21 U.S.C. § 355(b)(3).

3. The Hatch-Waxman Act provides for a litigation process unique to generic drugs. Pursuant to the statute, it is an “artificial” or “paper” act of infringement to submit an ANDA for a drug, the use of which is claimed in a patent, with the purpose of marketing that drug before the patent expires. 35 U.S.C. § 271(e)(2)(A).

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4. The '148, '625, and '678 patents (the “Bosulif Patents”) are listed in the Orange Book with respect to the approved innovator drug product Bosulif[®], and the filing of an ANDA seeking approval to market generic versions of Bosulif prior to the expiration of the Bosulif Patents is an act of infringement of those patents. 35 U.S.C. § 271(e)(2)(A).

5. Under 35 U.S.C. § 271(e)(2)(A), the “infringement inquiry” is “whether, if a particular drug *were* put on the market, it *would* infringe the relevant patent” *Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 760 (Fed. Cir. 2016) (emphasis in original) (citing *Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.3d 1130, 1135 (Fed. Cir. 1995)); accord *Novartis Pharm. Corp. v. Par Pharm., Inc.*, 48 F. Supp. 3d 733, 738 (D. Del. 2014) (Andrews, J.), *aff’d sub nom. Novartis Pharm. Corp. v. Watson Labs., Inc.*, 611 F. App’x 988 (Fed. Cir. 2015) (“Under 35 U.S.C. § 271(e)(2)(A), a court must determine whether, if the drug were approved based upon the ANDA, the manufacture, use, or sale of that drug would infringe the patent in the conventional sense.” (internal annotations omitted) (citation omitted)).

6. The patentee “has the burden of proving infringement by a preponderance of the evidence.” *Novartis*, 48 F. Supp. 3d at 738 (citation omitted). The infringement inquiry is “based on consideration of all the relevant evidence, including the ANDA filing, other materials submitted by the accused infringer to the FDA, and other evidence provided by the parties.” *Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002) (citation omitted)). *See also Vanda Pharm. Inc. v. West-Ward Pharm. Int’l Ltd.*, 887 F.3d 1117, 1125 (Fed. Cir. 2018); *Sunovion Pharm., Inc. v. Teva Pharm. USA, Inc.*, 731 F.3d 1271, 1278 (Fed. Cir. 2013).

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B. Whether Plaintiffs Have Proved by a Preponderance of the Evidence that (i) Physicians Prescribing and Patients Self-Administering Sun’s ANDA Products Will Directly Infringe Claim 7 of the ’148 Patent; and (ii) Sun Will Directly Infringe the Asserted Claims of the ’625 and ’678 Patents

7. “Infringement is a question of fact.” *Sunovion*, 731 F.3d at 1275 (citation omitted); *see also Pazandeh v. Yamaha Corp. of Am.*, 718 F. App’x 975, 979 (Fed. Cir. 2018). In order to prove infringement, a patentee must “prove by a preponderance of the evidence that the accused product met each and every limitation” of the asserted claims. *Catalina Lighting, Inc. v. Lamps Plus, Inc.*, 295 F.3d 1277, 1285 (Fed. Cir. 2002) (citation omitted).

8. To show infringement of a patent, a patentee must “supply sufficient evidence to prove that the accused product or process contains, either literally or under the doctrine of equivalents, every limitation of the properly construed claim.” *Seal-Flex, Inc. v. Athletic Track & Court Constr.*, 172 F.3d 836, 842 (Fed. Cir. 1999), *cited in Eli Lilly & Co. v. Hospira, Inc.*, 933 F.3d 1320, 1328 (Fed. Cir. 2019). A patent claim is literally infringed when each element of the claim is literally found in the accused product. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 384-91 (1996). Direct infringement of an apparatus claim “requires that each and every limitation set forth in a claim appear in an accused product.” *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1310 (Fed. Cir. 2005) (citation omitted), *cited in Centrak, Inc. v. Sonitor Techs., Inc.*, 915 F.3d 1360, 1371 (Fed. Cir. 2019) and *LifeNet Health v. LifeCell Corp.*, 837 F.3d 1316, 1325 (Fed. Cir. 2016).

9. Direct infringement under 35 U.S.C. § 271(a) occurs where all steps of a claimed method are performed by or attributable to a single entity. *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1022 (Fed. Cir. 2015). *See also Medgraph, Inc. v. Medtronic, Inc.*, 843 F.3d 942, 947 (Fed. Cir. 2016) (highlighting that to show attribution, evidence would have to allow a finding that a party “conditions participation in an activity or receipt of a benefit

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upon performance of a step or steps of a patented method and establishes the manner and timing of performance”).

10. The product labeling for generic medications manufactured pursuant to an ANDA is regulated by the FDA and governed by federal regulations, which require the inclusion of Prescribing Information that recommends to healthcare providers when, how, and on whom to use the drug. *See* U.S. Dept. of Health & Human Services, FDA, *Guidance For Industry: Labeling For Human Prescription Drug & Biologic Prods.—Implementing The PLR Content & Format Requirements* 2 (2013). The FDA requires that the Full Prescribing Information must contain, as section 2 of the label, instructions for “Dosage and administration,” which “must state the recommended dose and, as appropriate: (A) [t]he dosage range, . . . (D) [t]he intervals recommended between doses, (E) [t]he optimal method of titrating dosage, [and] (F) [t]he usual duration of treatment when treatment duration should be limited” 21 C.F.R. § 201.57(c)(3)(i). Furthermore, other “[d]osing regimens must not be implied or suggested in other sections of the labeling if not included in” section 2 of the Full Prescribing Information. 21 C.F.R. § 201.57(c)(3)(ii).

11. If the FDA determines that patient labeling could help prevent serious adverse effects, there are serious risks (relative to benefits) of which patients should be made aware, or the drug product is important to health and patient adherence to directions for use is crucial to the drug’s effectiveness, then that drug product must also be accompanied by a Medication Guide to provide information that “is necessary to patients’ safe and effective use of drug products.” 21 C.F.R. § 208.1(b)-(c). This guide is “FDA-approved patient labeling,” 21 C.F.R. § 208.3(h), which the distributor of any drug product must provide (or provide means to produce) in sufficient numbers “to permit the authorized dispenser to provide a Medication Guide to each

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patient receiving a prescription for the drug product.” 21 C.F.R. § 208.24(b)(1), (2). If the Medication Guide cannot be fitted on the drug product’s packaging, the drug product’s label must “instruct the authorized dispenser to provide a Medication Guide to each patient to whom the drug product is dispensed, and shall state how the Medication Guide is provided.” 21 C.F.R. § 208.24(d). Authorized dispensers must, in turn, provide a Medication Guide to each patient unless the FDA specifically exempts the drug product at issue or the licensed practitioner who prescribed the drug product specifically states that receiving the Medication Guide is not in the particular patient’s best interest, except that in the latter case the patient shall receive that Medication Guide upon request. 21 C.F.R. §§ 208.24(e), 208.26.

12. In the context of Hatch-Waxman litigation, it is permissible to consider evidence beyond the accused infringer’s ANDA unless that ANDA is dispositive of infringement. *See Ferring B.V. v. Watson Labs., Inc.-Florida*, 764 F.3d 1401, 1409 (Fed. Cir. 2014) (“In cases in which the ANDA specification does not resolve the infringement question in the first instance, we have endorsed the district court’s reference to relevant evidence, including biobatch data and actual samples of the proposed generic composition that the ANDA filer had submitted to the FDA.”); *Sunovion*, 731 F.3d at 1279-80. To support a finding of infringement, it is permissible to compare an allegedly infringing product to a commercial embodiment of the asserted claims. *TEK Global, S.R.L. v. Sealant Sys. Int’l, Inc.*, 920 F.3d 777, 788 (Fed. Cir. 2019) (“[W]hen a commercial product meets all the claim limitations, then a comparison [of the accused product] to that [commercial] product may support a finding of infringement.”) (quoting *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, 616 F.3d 1283, 1288-89 (Fed. Cir. 2010)).

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C. Whether Plaintiffs Have Proved by a Preponderance of the Evidence that Sun’s ANDA Products Will Cause Indirect Infringement of Claim 7 of the ’148 Patent

i. Whether Plaintiffs Have Proved by a Preponderance of the Evidence that the Proposed Labeling for Sun’s ANDA Products Will Induce Infringement of Claim 7 of the ’148 Patent

13. Pursuant to 35 U.S.C. § 271(b), “[w]hoever actively induces infringement of a patent shall be liable as an infringer.”

14. “[L]iability for induced infringement under § 271(b) must be predicated on direct infringement.” *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357, 1363-64 (Fed. Cir. 2017) (internal quotations and citation omitted).

15. “Section 271(e)(2) may support an action for induced infringement.” *Forest Labs., Inc. v. Ivax Pharm., Inc.*, 501 F.3d 1263, 1272 (Fed. Cir. 2007) (citing *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1331 (Fed. Cir. 2003)).

16. “[L]iability for inducing infringement attaches only if the defendant knew of the patent and that ‘the induced acts constitute patent infringement.’” *Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920, 1926 (2015) (quoting *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011)), *cited in Omega Patents, LLC v. CalAmp Corp.*, 920 F.3d 1337, 1349 (Fed. Cir. 2019). “When a person actively induces another to take some action, the inducer obviously knows the action that he or she wishes to bring about.” *Global-Tech*, 563 U.S. at 760.

17. Inducement is present where active steps taken to encourage direct infringement, such as instructing how to engage in an infringing use, show intent that the product be used to infringe. *See Metro-Goldwyn-Mayer Studios Inc. v. Grokster Ltd.*, 545 U.S. 913, 936 (2005), *cited in Global-Tech*, 563 U.S. at 763; *see also Vanda*, 887 F.3d at 1129 (“We have held that ‘[i]nducement can be found where there is ‘[e]vidence of active steps taken to encourage direct infringement,’ which can in turn be found in ‘advertising an infringing use or instructing how to

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engage in an infringing use.”) (quoting *Takeda Pharm. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 630-31 (Fed. Cir. 2015)).

18. “[L]iability for active inducement may be found where evidence . . . shows statements or actions directed to promoting infringement,” and actions such as “instructing how to engage in an infringing use” demonstrate “an affirmative intent that the product be used to infringe.” *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1059 (Fed. Cir. 2010) (internal quotations and citations omitted); *see also Forest Labs. Holdings Ltd. v. Mylan Inc.*, 206 F. Supp. 3d 957, 975 (D. Del. 2016) (“We have long held that the sale of a product specifically labeled for use in a patented method constitutes inducement to infringe that patent, and usually is also contributory infringement.” (quoting *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 435 F. App’x 917, 926 (Fed. Cir. 2011))).

19. In pharmaceutical cases, the label accompanying the drug may itself encourage, recommend, or promote infringement. *Sanofi v. Watson Labs., Inc.*, 875 F.3d 636, 644 (Fed Cir. 2017) (quoting *Takeda*, 785 F.3d at 631).

20. Moreover, the “contents of the label itself may permit the inference of specific intent to encourage, recommend, or promote infringement.” *Vanda*, 887 F.3d at 1129 (citing *Sanofi*, 875 F.3d at 646). Proof of intent may be established even if not every practitioner will prescribe in a manner that infringes. *Vanda*, 887 F.3d at 1132; *see also Eli Lilly v. Teva*, 845 F.3d at 1368-69 (explaining that “evidence that the product labeling that Defendants seek would inevitably lead some physicians to infringe establishes the requisite intent for inducement”).

21. The instructions in an ANDA applicant’s labeling need not lead to infringement by every patient taking medication in accordance with that labeling; a label is infringing if it

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provides instructions that, if followed, “would inevitably lead some consumers to practice the claimed method.” *AstraZeneca*, 633 F.3d at 1060, *cited in Vanda*, 887 F.3d at 1130.

ii. Whether Plaintiffs Have Proved by a Preponderance of the Evidence that Sun’s ANDA Products Are Especially Made or Adapted for Infringement Such that Sun Will Contribute to Infringement of Claim 7 of the ’148 Patent

22. “Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.” 35 U.S.C. § 271(c).

23. “Where an ANDA is involved, contributory infringement claims may be brought under section 271(e)(2).” *Wyeth v. Sandoz, Inc.*, 703 F. Supp. 2d 508, 522 (E.D.N.C. 2010) (citing *Allergan v. Alcon*, 324 F.3d at 1331 (“[I]n *Glaxo*, we did not limit the scope of section 271(e)(2) to direct infringement actions.”)).

24. A “substantial non-infringing use is any use that is not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental.” *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1337 (Fed. Cir. 2012) (internal quotations and citation omitted).

25. “We have long held that the sale of a product specifically labeled for use in a patented method constitutes inducement to infringe that patent, and usually is also contributory infringement.” *Eli Lilly v. Actavis*, 435 F. App’x at 926 (citing *AstraZeneca*, 633 F.3d at 1060).

26. The potential for unauthorized, off-label use of a drug product will not render a drug product a “staple article of commerce suitable for substantial noninfringing use” and “does not avoid infringement by a product that is authorized to be sold solely for the infringing use.”

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Eli Lilly v. Actavis, 435 F. App'x at 927; *see also Grunenthal GMBH v. Alkem Labs. Ltd.*, 919 F.3d 1333, 1340 (Fed. Cir. 2019) (“In a pharmaceutical case, the noninfringing use must be in accordance with the use for which the product is indicated.”); *Forest Labs. Holdings*, 206 F. Supp. 3d at 978 (“[A]n off-label use . . . cannot constitute a substantial non-infringing use.”); *Depomed, Inc. v. Actavis Elizabeth LLC*, No. CIV.A. 12-1358 JAP, 2014 WL 4215435, *22 (D.N.J. Aug. 25, 2014) (“Defendant argues that this element of the contributory infringement analysis (*i.e.*, that there are not significant noninfringing uses) has not been met due [to] the existence of a number of off-label uses . . . for the ANDA. However, because [the defendant] cannot expressly market its product for any of these uses, the Court finds this third element to be met.”).

D. Whether Sun Directly Infringed the Bosulif Patents by Submitting Its ANDA

27. Sun has directly infringed the asserted claims of the Bosulif Patents by submitting its ANDA application seeking approval to make, use and sell its generic bosutinib tablets prior to the expiration of the Bosulif Patents. *See* 35 U.S.C. § 271(e)(2)(A).

28. Upon FDA approval of its ANDA, Sun will infringe the asserted claims of the Bosulif Patents under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling its generic bosutinib tablets in the United States.

29. Upon FDA approval of Defendants’ ANDA, doctors prescribing and patients taking Defendants’ generic bosutinib tablets will directly infringe the asserted claim of the ’148 patent.

30. Upon FDA approval of Defendants’ ANDA, Defendants will induce infringement of the asserted claim of the ’148 patents under 35 U.S.C. § 271(b) by making, using, offering to sell, importing and/or selling Defendants’ generic bosutinib tablets in the United States.

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“Section 271(e)(2) may support an action for induced infringement.” *Forest Labs. v. Ivax*, 501 F.3d at 1272 (citing *Allergan v. Alcon*, 324 F.3d at 1331).

31. Upon FDA approval of Defendants’ ANDA, Defendants will contributorily infringe the asserted claims of the ’148 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Defendants’ generic bosutinib tablets in the United States.

II. WHETHER DEFENDANTS HAVE PROVEN THAT BY CLEAR AND CONVINCING EVIDENCE THAT THE ASSERTED CLAIMS OF THE BOSULIF PATENTS ARE INVALID

32. “Each claim of a patent” is “presumed valid.” 35 U.S.C. § 282(a). Thus, each of the asserted claims of the Bosulif Patents is presumed valid.

33. Because each claim of a patent is presumed valid, an accused infringer “must submit evidence supporting a conclusion of invalidity of each claim the challenger seeks to destroy.” *Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 942 (Fed. Cir. 1992) (citation omitted); *see also Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1260 (Fed. Cir. 2004).

34. “The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.” 35 U.S.C. § 282(a). Thus, Defendants have the burden of proving invalidity.

35. Defendants “bear[] the burden of proving invalidity by ‘clear and convincing evidence’” *Shire LLC v. Amneal Pharm., LLC*, 802 F.3d 1301, 1306 (Fed. Cir. 2015) (quoting *Microsoft Corp. v. I4I Ltd. P’ship*, 564 U.S. 91, 95 (2011)); *UCB, Inc. v. Accord Healthcare, Inc.*, 890 F.3d 1313, 1323 (Fed. Cir. 2018).

36. “The ‘clear and convincing’ standard is an intermediate standard which lies somewhere in between the ‘beyond a reasonable doubt’ and the ‘preponderance of the evidence’ standards of proof.” *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1359 n.5 (Fed. Cir. 2007)

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(citations omitted). “Although an exact definition is elusive, ‘clear and convincing evidence’ has been described as evidence that ‘place[s] in the ultimate factfinder an abiding conviction that the truth of its factual contentions are highly probable.’” *Id.* (citation omitted).

A. Whether Defendants Have Proven by Clear and Convincing Evidence that Claim 1 of the ’625 Patent and Claims 2 and 3 of the ’678 Patent Are Anticipated

37. A patent claim is anticipated “only if each and every element is found within a single prior art reference, arranged as claimed.” *Summit 6, LLC v. Samsung Elecs. Co., Ltd.*, 802 F.3d 1283, 1294 (Fed. Cir. 2015); *ATEN Int’l Co., Ltd. v. Uniclass Tech. Co., Ltd.*, 932 F.3d 1364, 1368 (Fed. Cir. 2019).

38. “A prior art reference anticipates a patent claim under 35 U.S.C. § 102(b) if it discloses every claim limitation. A reference may anticipate inherently if a claim limitation that is not expressly disclosed ‘is necessarily present, or inherent, in the single anticipating reference.’ The inherent result must inevitably result from the disclosed steps; ‘[i]nherency . . . may not be established by probabilities or possibilities.’” *In re Montgomery*, 677 F.3d 1375, 1379-80 (Fed. Cir. 2012) (citations omitted); *see also U.S. Water Servs., Inc. v. Novozymes A/S*, 843 F.3d 1345, 1350 (Fed. Cir. 2016).

39. In order for a prior art method to anticipate a polymorph claim the prior art must “necessarily and inevitably” produce the claimed polymorph. *See In re Depomed Patent Litig.*, No. 13-4507, 2016 WL 7163647, at *45-49 (D.N.J. Sept. 30, 2016), *aff’d sub nom. Grunenthal GMBH v. Alkem Labs. Ltd.*, 919 F.3d 1333 (Fed. Cir. 2019).

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B. Whether Plaintiffs Have Proven By a Preponderance of the Evidence that the '148 and '625 Patents Are Entitled to Invention Dates Prior to November 6, 2002 or, Alternatively, Prior to December 6, 2002

40. A patent owner may antedate a reference by proving earlier conception and reasonable diligence in reduction to practice. *ATI Techs. ULC v. Iancu*, 920 F.3d 1362, 1370 (Fed. Cir. 2019).

41. “Reasonable diligence must be shown throughout the entire critical period, which begins just prior to the competing reference’s effective date and ends on the date of the invention’s reduction to practice.” *Perfect Surgical Techniques, Inc. v. Olympus Am., Inc.*, 841 F.3d 1004, 1007 (Fed. Cir. 2016), *cited in ATI Techs. ULC*, 920 at 1369.

42. “A patent owner need not prove the inventor *continuously* exercised reasonable diligence throughout the critical period; it must show there was *reasonably continuous* diligence.” *Perfect Surgical*, 841 F.3d at 1009 (emphasis in original). “[A]n inventor is not required to work on reducing his invention to practice every day during the critical period. And periods of inactivity within the critical period do not automatically vanquish a patent owner’s claim of reasonable diligence. . . . In determining whether an invention antedates another, the point of the diligence analysis is not to scour the patent owner’s corroborating evidence in search of intervals of time where the patent owner has failed to substantiate some sort of activity. It is to assure that, in light of the evidence as a whole, ‘the invention was not abandoned or unreasonably delayed.’” *Id.* (citations omitted).

43. “Diligence is not negated if the inventor works on improvements and evaluates alternatives while developing an invention.” *ATI*, 920 F. 3d at 1372.

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C. Whether Plaintiffs Have Proven By a Preponderance of the Evidence that the Boschelli 2002 and Golas 2003 References Were the Work of the Inventors of the '148 and '625 Patents

44. “[O]ne’s own work is not prior art under § 102(a) even though it has been disclosed to the public in a manner or form which otherwise would fall under § 102(a).” *See Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 968 (Fed. Cir. 2014) (quoting *In re Katz*, 687 F.2d 450, 454 (C.C.P.A. 1982)). *See also EmeraChem Holdings, LLC v. Volkswagen Grp. of Am., Inc.*, 859 F.3d 1341, 1347 (Fed. Cir. 2017); *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1381 (Fed. Cir. 2005) (“[A]n inventor’s own work cannot be used to invalidate patents protecting his own later inventive activities”); *Application of Facius*, 408 F.2d 1396, 1406 (C.C.P.A. 1969) (“[C]ertainly one’s own invention, whatever the form of disclosure to the public, may not be prior art against oneself, absent a statutory bar.”).

D. Whether the Defendants Have Proven by Clear and Convincing Evidence that the Asserted Claims of the Bosulif Patents Are Invalid as Obvious

i. Obviousness in General

45. In order to establish that the patents-in-suit are invalid for obviousness under 35 U.S.C. § 103, Defendants must prove by clear and convincing evidence that on the relevant effective dates of the applications for the patents-in-suit “the differences between the claimed subject matter and the prior art [were] such that the subject matter as a whole would have been obvious at the time of invention to a person having ordinary skill in the art.” *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1303 (Fed. Cir. 2015).

46. A party seeking to invalidate a patent based on obviousness must demonstrate “by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.” *Procter & Gamble Co. v. Teva*

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Pharm. USA, Inc., 566 F.3d 989, 994 (Fed. Cir. 2009), *cited in Novartis Pharm. Corp. v. West-Ward Pharm. Int'l Ltd.*, 923 F.3d 1051, 1059 (Fed. Cir. 2019) and *Eli Lilly v. Teva*, 845 F.3d at 1372.

47. A patent is only invalid if the invention was obvious “before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.” 35 U.S.C. § 103.

48. The burden of proving invalidity “is constant and remains throughout the suit on the challenger” and “does not shift at any time to the patent owner.” *TP Labs., Inc. v. Prof'l Positioners, Inc.*, 724 F.2d 965, 971 (Fed. Cir. 1984).

49. The underlying facts that must be considered in determining whether the challenging party has met its burden of proof of obviousness by clear and convincing evidence are: (a) the scope and content of the prior art; (b) the level of ordinary skill in the art; (c) the differences between the prior art and the claims at issue; and (d) objective indicia of nonobviousness (or “secondary” considerations). *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 17-18 (1966).

50. A patent challenger must prove each of the *Graham* factors by clear and convincing evidence. *Apple Inc. v. Samsung Elecs. Co., Ltd.*, 839 F.3d 1034, 1062 (Fed. Cir. 2016); *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1351 (Fed. Cir. 1998); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 292 (Fed. Cir. 1985).

51. It is not sufficient to establish obviousness that there are pieces of the invention disclosed in the prior art which, if they were combined, would lead to the invention. There must be some reason to assemble the specific combination of elements that is the invention. *Intercontinental Great Brands LLC v. Kellogg N. Am. Co.*, 869 F.3d 1336, 1344 (Fed. Cir. 2017)

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(“The court should consider a range of real-world facts to determine ‘whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.’” (citing *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007))); *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143 (Fed. Cir. 1985); *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n.5 (Fed. Cir. 1986); *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1575 (Fed. Cir. 1987) (“Virtually all inventions are necessarily combinations of old elements. . . . The notion, therefore, that combination claims can be declared invalid merely upon finding similar elements in separate prior patents would necessarily destroy virtually all patents and cannot be the law under the statute”). *See also Plantronics, Inc. v. Aliph, Inc.*, 724 F.3d 1343, 1354 (Fed. Cir. 2013) (“An invention may be a combination of old elements disclosed in multiple prior art references.” (quoting *Cross Med. Prods.*, 535 F.3d at 1321)).

52. Even if the prior art discloses “all of the limitations of the asserted claims,” a challenger must “proffer evidence indicating why a person having ordinary skill in the art would combine the references to arrive at the claimed invention.” *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1366 (Fed. Cir. 2012); *see also Cumberland Pharm. Inc. v. Mylan Institutional LLC*, 846 F.3d 1213, 1221-22 (Fed. Cir. 2017); *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1374 (Fed. Cir. 2008).

53. Fact-finders must be aware “of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning.” *KSR*, 550 U.S. at 421 (citing *Graham*, 383 U.S. at 36).

54. “The inventor’s own path itself never leads to a conclusion of obviousness; that is hindsight. What matters is the path that the person of ordinary skill in the art would have followed, as evidenced by the pertinent prior art.” *Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.*, 678

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F.3d 1280, 1296 (Fed. Cir. 2012), *cited in Millennium Pharm., Inc. v. Sandoz Inc.*, 862 F.3d 1356, 1367 (Fed. Cir. 2017); *see also Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008) (“Of course, [hindsight] reasoning is always inappropriate for an obviousness test based on the language of Title 35 that requires the analysis to examine ‘the subject matter as a whole’ to ascertain if it ‘*would have been obvious at the time the invention was made.*’” (emphasis in original) (quoting 35 U.S.C. § 103(a) (pre-AIA))); *Life Techs., Inc. v. Clontech Labs., Inc.*, 224 F.3d 1320, 1325 (Fed. Cir. 2000) (“[T]he path that leads an inventor to the invention is expressly made irrelevant to patentability by statute.”).

55. “In retrospect, [the inventor’s] pathway to the invention, of course, seems to follow the logical steps to produce these properties, but at the time of invention, the inventor’s insights, willingness to confront and overcome obstacles, and yes, even serendipity, cannot be discounted.” *Ortho-McNeil*, 520 F.3d at 1364. “One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to depreciate the claimed invention.” *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988), *cited in Ecolchem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1371 (Fed. Cir. 2000).

56. “When the prior art was before the examiner during prosecution of the application, there is a particularly heavy burden in establishing invalidity.” *Impax Labs., Inc. v. Aventis Pharm. Inc.*, 468 F.3d 1366, 1378 (Fed. Cir. 2006) (citing *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1467 (Fed. Cir. 1990)); *see also Pfizer Inc. v. Watson Pharm., Inc.*, 920 F. Supp. 2d 552, 563 (D. Del. 2013) (Andrews, J.) (While “the standard of proof does not depart from that of clear and convincing evidence, a party challenging validity shoulders an enhanced burden if the invalidity argument relies on the same prior art considered during examination by the [PTO].”).

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57. A defendant cannot prove that a claim is obvious by showing that the particular combination was “obvious to try” unless, at a minimum, “there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions,” and the combination “leads to the anticipated success” *KSR*, 550 U.S. at 421.

58. “Evidence of obviousness, especially when that evidence is proffered in support of an ‘obvious-to-try’ theory, is insufficient unless it indicates that the possible options skilled artisans would have encountered were ‘finite,’ ‘small,’ or ‘easily traversed’ and that skilled artisans would have had a reason to select the route that produced the claimed invention.” *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1072 (Fed. Cir. 2012) (citations omitted).

59. For a patent challenger to establish obviousness of a claimed polymorph, “it is insufficient to allege a general motivation to discover an undefined solution that could take many possible forms.” *In re Depomed Patent Litig.*, 2016 WL at *53 (quoting *Cephalon, Inc. v. Watson Pharm., Inc.*, 939 F. Supp. 3d 456, 500 (D. Del. 2013)). In addition to proving a motivation to combine, a patent challenger must also “prove a reasonable expectation of success in arriving at [the claimed polymorph form] or, relatedly, it would have been obvious to try to find [the claimed polymorph form].” *Grunenthal v. Alkem*, 919 F.3d at 1341.

ii. Reasonable Expectation of Success

60. “An obviousness determination requires that a skilled artisan would have perceived a reasonable expectation of success in making the invention in light of the prior art.” *Amgen Inc. v. F. Hoffman-La Roche Ltd*, 580 F.3d 1340, 1362 (Fed. Cir. 2009), *cited in* *Howmedica Osteonics Corp. v. Zimmer, Inc.*, 640 F. App’x 951, 961 (Fed. Cir. 2016).

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61. “[O]ne must have a motivation to combine accompanied by a reasonable expectation of achieving what is claimed in the patent-at-issue.” *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016).

62. “To the extent an art is unpredictable, as the chemical arts often are, . . . solutions are less likely to be genuinely predictable.” *Eisai Co. Ltd. v. Dr. Reddy’s Labs., Ltd.*, 533 F.3d 1353, 1359 (Fed. Cir. 2008), *cited in BASF Corp. v. Enthone, Inc.*, 749 F. App’x 978, 983 (Fed. Cir. 2018).

iii. Teaching Away

63. When evaluating nonobviousness, the entire teachings of the prior art must be considered, “including that which might lead away from the claimed invention.” *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988).

64. “It is impermissible . . . to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.” *Application of Wesslau*, 353 F.2d 238, 241 (C.C.P.A. 1965); *see also Eli Lilly v. Actavis*, 435 F. App’x at 921; *In re Vaidyanathan*, 381 F. App’x 985, 992 (Fed. Cir. 2010) (“[P]rior art reference should be considered in its entirety for what it fairly suggests to one of ordinary skilled in the art.”); *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 448 (Fed. Cir. 1986).

65. “[W]hen the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious.” *KSR*, 550 U.S. at 416.

66. Whether a reference teaches away is determined by considering the prior art as a whole from the view of a person of ordinary skill in the art. *In re Hedges*, 783 F.2d 1038, 1041

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(Fed. Cir. 1986) (“[T]he prior art as a whole must be considered. The teachings are to be viewed as they would have been viewed by one of ordinary skill.” (citations omitted)). *See also Otsuka*, 678 F.3d at 1296 (“Taken as a whole, . . . the prior art taught away from using [a lead compound] as a starting point for further antipsychotic research.”).

67. A reference teaches away when it suggests that a combination of elements found in the prior art is unlikely to be productive of the result sought or when one skilled in the art “would be led in a direction divergent from the path that was taken by the [patentee].” *Pozen Inc. v. Par Pharm., Inc.*, 696 F.3d 1151, 1164-1165 (Fed. Cir. 2012). This is demonstrated where the prior art “suggests that the line of development flowing from the reference’s disclosure is unlikely to be productive of the result sought by the applicant” *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (citation omitted), *cited in Bayer Pharma AG v. Watson Labs., Inc.*, 874 F.3d 1316, 1327 (Fed. Cir. 2017) and *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1344 (Fed. Cir. 2012).

68. Where the prior art teaches away from the claimed invention, claims to the unexpected properties of the claimed invention, “even if inherent in that [invention],” do not render it obvious, because “previously *unknown* and *unexpected* properties of a new and nonobvious [invention] constitute additional, objective evidence of nonobviousness.” *Allergan v. Sandoz*, 796 F.3d at 1307 (emphasis in original).

69. Whether a prior art reference teaches away from the claimed invention is a question of fact. *Santarus*, 694 F.3d at 1354; *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006).

iv. Level of Ordinary Skill in the Art

70. Obviousness is judged from the perspective of “a person having ordinary skill in the art to which the claimed invention pertains.” 35 U.S.C. § 103.

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71. “The ‘person of ordinary skill in the art’ is a theoretical construct used in determining obviousness under § 103, and is not descriptive of some particular individual.” *Endress + Hauser, Inc. v. Hawk Measurement Sys. Pty. Ltd.*, 122 F.3d 1040, 1042 (Fed. Cir. 1997); *cited in Norgren Inc. v. Int’l Trade Comm’n*, 699 F.3d 1317, 1325 (Fed. Cir. 2012).

72. The purpose of conducting the obviousness analysis from the perspective of one skilled in the art “is to assure an appropriate perspective of the decisionmaker, and to focus on conditions as they existed when the invention was made.” *Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 956 (Fed. Cir. 1997). “Good ideas may well appear ‘obvious’ after they have been disclosed, despite having been previously unrecognized.” *Id.*, *cited in Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, 695 F.3d 1285, 1298 (Fed. Cir. 2012).

73. “Factors that may be considered in determining level of skill include: type of problems encountered in art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field.” *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1376 (Fed. Cir. 2012) (citation omitted).

74. The Federal Circuit has made clear that while the educational background of the inventors themselves may be a factor in determining the level of ordinary skill in the art, it is not conclusive. *Bausch & Lomb*, 796 F.2d at 449-50; *see also Hologic, Inc. v. Minerva Surgical, Inc.*, 764 F. App’x 873, 879 (Fed. Cir. 2019); *Daiichi Sankyo Co., Ltd. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007) (providing a list of factors including the education level of the inventor and emphasizing that the factors “are not exhaustive but are merely a guide to determining the level of ordinary skill in the art”).

EXHIBIT 4**v. Secondary Considerations of Nonobviousness**

75. Secondary considerations (objective indicia) of nonobviousness are further evidence that a patented invention is nonobvious. *Institut Pasteur & Universite Pierre Et Marie Curie v. Focarino*, 738 F.3d 1337, 1346 (Fed. Cir. 2013) (Secondary considerations “enable[] the court to avert the trap of hindsight.”); *Crocs, Inc. v. Int’l Trade Comm’n*, 598 F.3d 1294, 1310 (Fed. Cir. 2010) (Secondary considerations “may often establish that an invention appearing to have been obvious in light of the prior art was not.”); *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 667 (Fed. Cir. 2000) (Secondary considerations “may be sufficient to overcome a prima facie case of obviousness.”); *see also Graham*, 383 U.S. at 36 (The secondary considerations of nonobviousness “focus attention on economic and motivational rather than technical issues and are, therefore, more susceptible of judicial treatment than are the highly technical facts often present in patent litigation.”).

76. “[S]econdary considerations, when present, must be considered in determining obviousness.” *Ruiz*, 234 F.3d at 667; *see also UCB, Inc. v. Accord Healthcare, Inc.*, 201 F. Supp. 3d 491, 544 (D. Del. 2016), *aff’d*, 890 F.3d 1313 (Fed. Cir. 2018) (“objective evidence ‘must be considered *before* a conclusion on obviousness is reached and is not merely ‘icing on the cake’” (quoting *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380 (Fed. Cir. 1986) (emphasis in original))).

77. For a secondary consideration to be accorded substantial weight, the patentee “must establish a nexus between the evidence and the merits of the claimed invention.” *Bayer Pharma AG v. Watson Labs., Inc.*, 212 F. Supp. 3d 489, 525 (D. Del. 2016) (citation omitted).

78. “Secondary considerations ‘may often be the most probative and cogent evidence in the record’ relating to obviousness.” *UCB*, 201 F. Supp. 3d at 527 (quoting *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983)).

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79. FDA approval “can be relevant in evaluating the objective indicia of nonobviousness.” *Leo Pharm. Prods., Ltd. v. Rea*, 726 F.3d 1346, 1358 (Fed. Cir. 2013); *see also Warner Chilcott Co., LLC v. Lupin Ltd.*, No. CIV.A. 11-5048 JAP, 12-2928 JAP, 2014 WL 202659, at *22 (D.N.J. Jan. 17, 2014), *aff’d*, 580 F. App’x 911 (Fed. Cir. 2014).

a. Long-Felt Need and Failure of Others

80. One of the objective indicia of nonobviousness is a long-felt need for an invention that addresses the problem solved by the patent-in-suit. *Graham*, 383 U.S. at 17 (the existence of “long felt but unsolved needs” is a secondary consideration of nonobviousness); *In re Depomed, Inc.*, 680 F. App’x 947, 951 (Fed. Cir. 2017); *In the Matter of Mahurkar Double Lumen Hemodialysis Catheter Patent Litig.*, 831 F. Supp. 1354, 1378 (N.D. Ill. 1993), *aff’d*, 71 F.3d 1573 (Fed. Cir. 1995) (“The existence of an enduring, unmet need is strong evidence that the invention is novel, not obvious, and not anticipated. If people are clamoring for a solution, and the best minds do not find it for years, that is practical evidence—the kind that can’t be bought from a hired expert, the kind that does not depend on fallible memories or doubtful inferences—of the state of knowledge.”).

81. The finder of fact must “look to the filing date of the challenged invention to assess the presence of a long-felt and unmet need.” *Procter & Gamble*, 566 F.3d at 998; *see also Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1332 (Fed. Cir. 2009) (“Evidence that an invention satisfied a long-felt and unmet need that existed on the patent’s filing date is a secondary consideration of nonobviousness.”).

82. Evidence of a long-felt and unsolved need in the industry for the solution offered by the patented invention supports a finding that the invention would not have been obvious at the time the invention was made. *See, e.g., Georgia-Pacific Corp. v. U.S. Gypsum Co.*, 195 F.3d

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1322, 1330 (Fed. Cir. 1999); *Procter & Gamble*, 566 F.3d at 998 (finding a long-felt unmet need was present when osteoporosis was recognized as a serious disease and existing treatments were inadequate); *Bayer Pharma*, 212 F. Supp. 3d at 525-526 (decades of attempts to create successful treatment supported finding of long-felt need and failure of others).

83. An FDA grant of priority review for an innovator's NDA is evidence of a long-felt but unmet need. *See Cadence Pharm., Inc. v. Exela Pharma Scis., LLC*, No. CV 11-733-LPS, 2013 WL 11083853, at *29 (D. Del. Nov. 14, 2013), *aff'd*, 780 F.3d 1364 (Fed. Cir. 2015).

84. A patented method of treatment need not "solve the problem for all people" in order to show a long-felt need, so long as it proves "effective at [treating] a segment of the population who had previously gone without relief" *UCB*, 201 F. Supp. 3d at 538.

85. Another one of the objective indicia of the nonobviousness is the failure of others to develop a solution that effectively addresses the problem solved by the patent-in-suit. *Graham*, 383 U.S. at 36 (the "failure of others" is a secondary consideration of nonobviousness); *In re Depomed, Inc.*, 680 F. App'x at 951; *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1354 (Fed. Cir. 2003) ("[T]here can be little better evidence negating an expectation of success than actual reports of failure." (citation omitted)); *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1285 (Fed. Cir. 2000) ("[F]ailed attempts by others could be determinative on the issue of obviousness.").

86. "Evidence that others tried but failed to develop a claimed invention may carry significant weight in an obviousness inquiry." *In re Cyclobenzaprine*, 676 F.3d at 1081-83 (reversing district court's finding of obviousness based, in part, on its failure to consider evidence of long-felt need and failure of others). *See also Millennium Pharm.*, 862 F.3d at 1369

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n.5 (“[E]vidence that is particularly probative of obviousness when it demonstrates . . . that others tried but failed to satisfy that demand . . .”).

87. A long period of time prior to the application for the patent-in-suit during which many tried and failed to develop the claimed invention supports the conclusion that a patent is nonobvious. *See Warner Chilcott*, 2014 WL at *22, *aff’d*, 580 F. App’x 911 (Fed. Cir. 2014) (period of 30 years during which only one low-dose oral contraceptive was FDA approved supported conclusion that patent on second low-dose oral contraceptive was nonobvious).

b. Unexpected Results

88. “One way for a patent applicant to rebut a *prima facie* case of obviousness is to make a showing of ‘unexpected results,’ *i.e.*, to show that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected.” *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995), *cited in Forest Labs., LLC v. Sigmapharm Labs., LLC*, 918 F.3d 928, 937 (Fed. Cir. 2019); *see also Leo Pharm.*, 726 F.3d at 1358 (“Unexpected results are useful to show the ‘improved properties provided by the claimed compositions are much greater than would have been predicted.’” (citation omitted)).

89. “The basic principle behind this rule is straightforward—that which would have been surprising to a person of ordinary skill in a particular art would not have been obvious.” *In re Soni*, 54 F.3d at 750, *cited in Forest Labs.*, 918 F.3d at 937. “The principle applies most often to the less predictable fields, such as chemistry, where minor changes in a product or process may yield substantially different results.” *In re Soni*, 54 F.3d at 750; *see also Procter & Gamble*, 566 F.3d at 997-98 (affirming a district court’s finding that evidence of unexpectedly improved properties of the claimed drug’s potency and toxicity were sufficient to show unexpected results).

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90. Unexpected results that inherently flow from a claimed invention are evidence of nonobviousness and need not be described or proven in the text of the patent. *See Knoll Pharm. Co. v. Teva Pharm. USA, Inc.*, 367 F.3d 1381, 1385 (Fed. Cir. 2004); *Genetics Inst., LLC v. Novartis Vaccines & Diagnostics, Inc.*, 655 F.3d 1291, 1307-08 (Fed. Cir. 2011) (indicating Federal Circuit precedent “contains no such requirement” for unexpected results to be predicted in the patent specification), *cited in Sanofi-Aventis Deutschland GmbH v. Glenmark Pharm. Inc., USA*, 748 F.3d 1354, 1360 (Fed. Cir. 2014).

91. Evidence, such as test results, created after the patent’s filing or issue date may be considered to show that at the time of the invention one of ordinary skill in the art would have found the results achieved by the claimed invention to be unexpected. *See Knoll*, 367 F.3d at 1385; *see also Genetics Inst.*, 655 F.3d at 1307.

E. Whether the Defendants Have Proven by Clear and Convincing Evidence that the Bosulif Patents Are Invalid for Lack of Enablement

92. The statutory basis for the enablement requirement is found in 35 U.S.C. § 112 ¶ 1 (pre-AIA), which states (emphasis added) that:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms *as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same*

93. Enablement is a question of law based on underlying factual inquiries. *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1384 (Fed. Cir. 2013); *In re ’318 Patent Infringement Litig.*, 583 F.3d 1317, 1323 (Fed. Cir. 2009); *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1070 (Fed. Cir. 2005); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1334 (Fed. Cir. 2003).

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94. Enablement is determined as of the filing date of the patent application. *Wyeth & Cordis Corp.*, 720 F.3d at 1384; *Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co.*, 308 F.3d 1167, 1185 (Fed. Cir. 2002).

95. “To prove that a claim is invalid for lack of enablement, a challenger must show by clear and convincing evidence that a person of ordinary skill in the art would not be able to practice the claimed invention without ‘undue experimentation.’” *Allergan v. Sandoz*, 796 F.3d at 1309 (quoting *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988)); *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1375 (Fed. Cir. 2017).

96. “While every aspect of a generic claim certainly need not have been carried out by the inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.” *Alcon, Inc. v. Teva Pharm. USA, Inc.*, 664 F. Supp. 2d 443, 469 (D. Del. 2009) (quoting *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997)).

97. “The specification need not teach what is well known in the art.” *Alcon v. Teva*, 664 F. Supp. 2d at 469 (citation omitted); *see also Visual Memory LLC v. NVIDIA Corp.*, 867 F.3d 1253, 1261 (Fed. Cir. 2017) (“[A] patent need not teach, and preferably omits, what is well known in the art.” (citation omitted)). A reasonable amount of experimentation may be required, so long as such experimentation is not undue. *Wands*, 858 F.2d at 736-37.

98. Several factors may be considered when determining whether practicing a patent’s disclosures requires “undue experimentation”: “(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of

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the claims.” *Cephalon, Inc. v. Watson Pharm., Inc.*, 707 F.3d 1330, 1336 (Fed. Cir. 2013) (citing *Wands*, 858 F.2d at 737).

99. A “reasonable amount of routine experimentation required to practice a claimed invention does not violate the enablement requirement,” and “[u]nsubstantiated statements indicating that experimentation would be ‘difficult’ and ‘complicated’ are not sufficient” to show a lack of enablement. *Cephalon*, 707 F.3d at 1336, 1339.

100. “There is . . . no hard and fast rule that examples are necessary to enable an invention for a specific use.” *Glaxo Grp. Ltd. v. Teva Pharm. USA, Inc.*, No. C.A.02-219 GMS, 2004 WL 1875017, at *16 (D. Del. Aug. 20, 2004). It is proper to find method of treatment claims enabled where the patent “describes the utility [of the claimed method of treatment], and that the utility is correctly described.” *Eli Lilly v. Actavis*, 435 F. App’x at 923-27 (holding claims enabled where patent taught how to make and use the compounds through statements of the compound’s effectiveness in its specification, while only disclosing a range of doses that would be therapeutically effective).

F. Whether the Defendants Have Proven by Clear and Convincing Evidence that the ’148 and ’625 Patents Are Invalid for Lack of Written Description

101. Whether the Defendants have proven by clear and convincing evidence that the asserted claims of the ’148 and ’625 patents are invalid for lack of written description.

102. Compliance with the written description requirement is a question of fact. *Nuvo Pharm. (Ir.) Designated Activity Co. v. Dr. Reddy’s Labs. Inc.*, 923 F.3d 1368, 1376 (Fed. Cir. 2019) (citation omitted); *Invitrogen v. Clontech*, 429 F.3d at 1072.

103. “The purpose of the written description requirement is to require an inventor to disclose his invention to the public in such a manner as to allow a person of skill in the art to

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recognize that the patentee invented what is claimed.” *Tobinick v. Olmarker*, 753 F.3d 1220, 1225 (Fed. Cir. 2014) (internal quotations and citations omitted).

104. The “critical inquiry is whether the patentee has provided a description that in a definite way identifies the claimed invention in sufficient detail that a person of ordinary skill would understand that the inventor was in possession of it at the time of filing”; it “requires an objective inquiry into the four corners of the specification.” *Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1190-91 (Fed. Cir. 2014) (internal quotations and citations omitted); *see also Avanir Pharm., Inc. v. Actavis S. Atl. LLC*, 36 F. Supp. 3d 475, 498 (D. Del. 2014), *aff’d sub nom. Avanir Pharm. Inc. v. Par Pharm. Inc.*, 612 F. App’x 613 (Fed. Cir. 2015) (“Accordingly, the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” (internal quotations and citation omitted)).

105. “[W]hen examining the written description for support for the claimed invention . . . the exact terms appearing in the claim need not be used *in haec verba*.” *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1345 (Fed. Cir. 2016) (internal quotations and citation omitted). “We have not required more for an adequate written description that matches claim scope.” *GlaxoSmithKline LLC v. Banner Pharmacaps, Inc.*, 744 F.3d 725, 731 (Fed. Cir. 2014).

106. “[T]he written description requirement does not demand either examples or an actual reduction to practice; a constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement.” *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010). “Given the case law that an invention does not actually have to be used, or even made, in order to satisfy the written description

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requirement, clinical testing cannot be required to satisfy the written description requirement.” *Alcon Research, Ltd. v. Apotex Inc.*, 790 F. Supp. 2d 868, 943 (S.D. Ind. 2011), *aff’d and rev’d in part on other grounds*, 687 F.3d 1362 (Fed. Cir. 2012). *See also In re ’318 Patent Infringement Litig.*, 583 F.3d at 1324-25.

107. “Under the doctrine of inherent disclosure, when a specification describes an invention that has certain undisclosed yet inherent properties, that specification serves as adequate written description to support a subsequent patent application that explicitly recites the invention’s inherent properties.” *Yeda Research & Dev. Co., Ltd. v. Abbott GMBH & Co. KG*, 837 F.3d 1341, 1345 (Fed. Cir. 2016). *See also Amgen Inc. v. Sanofi*, No. CV 14-1317-RGA, 2019 WL 4058927, at *17 (D. Del. Aug. 28, 2019) (Andrews, J.) (rejecting challenge to jury instruction that provided:

Under the doctrine of inherent disclosure, when a specification describes an invention that has certain undisclosed yet inherent properties, those inherent properties may be relied upon for written description support. To be inherent, the feature that is alleged to have been inherent must necessarily have existed in the specification. The fact that the feature is likely to have existed is not sufficient. It is not required, however, that persons of ordinary skill recognize or appreciate the inherent disclosure at the time the January 9, 2008 application was filed.)

G. Whether the Defendants Have Proven by Clear and Convincing Evidence that the Bosulif Patents Are Invalid for Indefiniteness

108. Definiteness is a question of law that sometimes involves subsidiary factual findings. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 838 (2015).

109. “Keeping in mind that ‘patents are not addressed to lawyers, or even to the public generally, but rather to those skilled in the relevant art,’ the patent claims ‘must be precise enough to afford clear notice of what is claimed, thereby appris[ing] the public of what is still open to them.’” *Eidos Display, LLC v. AU Optronics Corp.*, 779 F.3d 1360, 1364 (Fed. Cir. 2015), *cert. denied sub nom. Chunghwa Picture Tubes, Ltd. v. Eidos Display, LLC*, 136 S. Ct.

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502 (2015) (quoting *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2128 (2014)); *see also One-E-Way, Inc. v. Int’l Trade Comm’n*, 859 F.3d 1059, 1063 (Fed. Cir. 2017).

110. The purpose of this requirement is to avoid the creation of a “zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims.” *Nautilus*, 134 S. Ct. at 2129 (citation omitted), *cited in Trusted Knight Corp. v. Int’l Bus. Mach. Corp.*, 681 F. App’x 898, 903 (Fed. Cir. 2017).

111. The definiteness requirement therefore mandates “that a patent’s claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty.” *Nautilus*, 134 S. Ct. at 2129, *cited in One-E-Way*, 859 F.3d at 1063. While this standard “mandates clarity” it also recognizes “that absolute precision is unattainable,” and “the certainty which the law requires in patents is not greater than is reasonable, having regard to their subject-matter.” *Nautilus*, 134 S. Ct. at 2129, *cited in Sonix Tech. Co., Ltd. v. Publ’ns Int’l, Ltd.*, 844 F.3d 1370, 1377 (Fed. Cir. 2017).

112. Claim terms are not indefinite for failing to provide “objective boundaries” absent evidence that “a POSA would need ‘clear guidelines’ or ‘explicit guidance’ or ‘the upper and lower limits’” in order to discern the scope of the claims. *UCB*, 201 F. Supp. 3d at 545 (citations omitted) (holding that the term “therapeutic composition,” which was construed as “suitable for use as a treatment regimen over an extended period of time (chronic administration),” was definite despite argument that “a POSA would not know ‘exactly how long’ a period is required to constitute ‘chronic administration’”).

H. Whether the Defendants Have Proven by Clear and Convincing Evidence that Claims 2 and 3 of the ’678 Patent Are Invalid in View of Claim 7 of the ’148 Patent for Obviousness-Type Double Patenting

113. Obviousness-type double patenting is a judicially-created doctrine that “prohibit[s] a party from obtaining an extension of the right to exclude through claims in a later

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patent that are not patentably distinct from claims in a commonly owned earlier patent.” *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 967 (Fed. Cir. 2011) (citation omitted). Between two commonly owned patents issued after the implementation of the Uruguay Round Agreements Act (URAA), claims of a later-expiring patent may be invalid for obviousness-type double patenting in view of claims of an earlier-expiring patent. *Gilead Sciences Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1216-17 (Fed. Cir. 2014), *cited in Novartis Pharm. Corp. v. Breckenridge Pharm. Inc.*, 909 F.3d 1335, 1358 (Fed. Cir. 2018) (“[W]e held in *Gilead* that the expiration date is the benchmark of obviousness-type double patenting . . . our opinion was limited to the context of when both patents in question are post-URAA patents.”).

114. Obviousness-type double patenting “is a question of law based on underlying facts” *Eli Lilly v. Teva*, 845 F.3d at 1375. To make a determination of obviousness-type double patenting, the court first “determin[es] the differences in the claims of the earlier and later patents,” and then “the court must determine if the alleged infringer has proven by clear and convincing evidence that the claims are not patentably distinct.” *Id.* (citing *Eli Lilly v. Barr Labs.*, 251 F.3d at 962, 968). “Even where a patent is found invalid for obviousness-type double patenting, though, a patentee may file a terminal disclaimer.” *Eli Lilly v. Teva*, 845 F.3d at 1375.. “A terminal disclaimer can indeed supplant a finding of invalidity for double patenting.” *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1375 (Fed. Cir. 2005).

I. The Bosulif Patents Are Valid

115. The Defendants have not shown by clear and convincing evidence that the asserted claims of any of the Bosulif Patents are invalid as obvious.

116. The Defendants have not shown by clear and convincing evidence that the asserted claims of the ’148 and ’625 patents are invalid for lack of enablement.

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117. The Defendants have not shown by clear and convincing evidence that the asserted claims of the '148 and '625 patents are invalid for lack of written description.

118. The Defendants have not shown by clear and convincing evidence that the asserted claims of the Bosulif Patents are invalid for indefiniteness.

119. The Defendants have not shown by clear and convincing evidence that claims 2 and 3 of the '678 Patent are invalid in view of claim 7 of the '148 Patent for obviousness-type double patenting.

III. WHETHER PLAINTIFFS ARE ENTITLED TO REMEDIES FOR DEFENDANTS' INFRINGEMENT OF THE PATENTS ASSERTED AGAINST THEM

A. Whether Plaintiffs Are Entitled to a Permanent Injunction Enjoining Sun from Infringing the Bosulif Patents During Their Terms

120. The Supreme Court has outlined the factors that are relevant to the injunction issue in a patent case, including (1) whether the patent holder has (or will) suffer irreparable injury or harm, (2) whether legal remedies are inadequate to compensate that injury, (3) a balance of hardships, and (4) the public interest. *See eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006), *cited in TEK Global*, 920 F.3d at 792 and *Amgen v. Sanofi*, 872 F.3d at 1381.

121. The loss of the right to exclude can constitute irreparable harm. *See Novozymes A/S v. Genencor Int'l, Inc.*, 474 F. Supp. 2d 592, 612 (D. Del. 2007). *Cf. Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1149 (Fed. Cir. 2011) ("While the patentee's right to exclude alone cannot justify an injunction, it should not be ignored either."). Another factor supporting a finding of irreparable harm is when the infringer will enter the patentee's market as a direct competitor. *See Sanofi-Aventis Deutschland GmbH v. Glenmark Pharm. Inc., USA*, 821 F. Supp. 2d 681, 694 (D.N.J. 2011), *aff'd*, 748 F.3d 1354 (Fed. Cir. 2014); *Amgen Inc. v. F. Hoffman-*

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LaRoche Ltd., 581 F. Supp. 2d 160, 212 (D. Mass. 2008), *aff'd in relevant part*, 580 F.3d 1340 (Fed. Cir. 2009); *Emory Univ. v. Nova Biogenetics, Inc.*, No. 1:06-CV-0141-TWT, 2008 WL 2945476, at *4-5 (N.D. Ga. July 25, 2008).

122. Monetary damages may be inadequate to compensate for injury when “[p]laintiffs have suffered a loss of market share, harm to reputation, and price erosion, all of which are facts that tend to establish the inadequacy of a legal remedy.” *Sanofi-Aventis*, 821 F. Supp. 2d at 694. In addition, the patent holder’s refusal to license the technology and to instead engage in extensive litigation demonstrates that monetary damages are inadequate. *Id.* Furthermore, monetary damages may be inadequate when the infringer will be the patentee’s sole competitor. *Id.*

123. When a defendant’s product is not on the market, the balance of hardships weighs in favor of the patentee. *See Novozymes*, 474 F. Supp. 2d at 613. Furthermore, the balance of the hardships does not favor the defendant when “[a]ny harms Defendants may suffer as a result of an injunction ‘were almost entirely preventable and were the result of its own calculated risk’” *Sanofi-Aventis*, 821 F. Supp. 2d at 695 (quoting *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006)).

124. The public has an interest in promoting and protecting patent rights. *Sanofi-Aventis*, 821 F. Supp. 2d at 696 (“If generic pharmaceutical companies were free to disregard patent rights and simply piggy back off the innovations of others, then the incentives the patent system is designed to promote, namely those that encourage continued investment in costly drug development, would disappear.”).

“[S]elling a lower priced product does not justify infringing a patent,” and although the Hatch–Waxman Act encourages making lower cost generic drugs available to the public, “it does not do so by entirely eliminating the exclusionary

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rights conveyed by pharmaceutical patents. Nor does the statutory framework encourage or excuse infringement of valid pharmaceutical patents.”

Id. (quoting *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005)).

B. Whether Plaintiffs Are Entitled to an Order Setting an FDA Approval Date for Sun’s ANDA Not Earlier Than the Expiration Dates of the Bosulif Patents

125. Where a defendant has submitted an ANDA that infringes a valid, Orange Book listed patent, “the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed.” 35 U.S.C. § 271(e)(4)(A); *see also* 21 U.S.C. § 355(j)(5)(B)(iii)(II).

126. Thus, if the product that the ANDA applicant is likely to market would infringe a valid patent claim, then “the patent owner is entitled to an order that FDA approval of the ANDA containing the paragraph IV certification not be effective until the patent expires.” *Bristol-Myers Squibb*, 69 F.3d at 1135, *cited in Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1245 (Fed. Cir. 2000).

C. Whether Plaintiffs Have Shown by a Preponderance of the Evidence that this is an Exceptional Case Warranting an Award of Attorneys’ Fees, Costs, and Expenses

127. “The court in exceptional cases may award reasonable attorney fees to the prevailing party.” 35 U.S.C. § 285.

128. “[A]n ‘exceptional’ case is simply one that stands out from others with respect to the substantive strength of a party’s litigating position . . . or the unreasonable manner in which the case was litigated.” *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S. Ct. 1749, 1756 (2014). There is “no precise rule or formula” for awarding attorneys’ fees under § 285. *Id.* (citation omitted). District Courts should “consider[] the totality of the circumstances.” *Id.* A

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district court's "discretion should be exercised in light of the considerations" underlying the grant of that discretion. *Id.* (internal quotations and citations omitted).

D. The Plaintiffs Are Entitled to the Relief Sought

129. Plaintiffs have shown by a preponderance of the evidence that they are entitled to a permanent injunction restraining and enjoining the Defendants (and all persons in active concert with the Defendants) from engaging in the commercial manufacture, use, offer for sale, or sale of each of Defendants' generic bosutinib tablets within the United States, or importation into the United States, during the terms of the Bosulif Patents.

130. Plaintiffs are entitled to an order setting an FDA approval date for Defendants' ANDA no earlier than the expirations of the Bosulif Patents or any later expiration of exclusivity to which Plaintiffs are or become entitled.

131. Plaintiffs have shown by a preponderance of the evidence that this is an exceptional case meriting an award of attorneys' fees, costs, and expenses.

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Pursuant to Local Rule 16.3(c)(5), Defendants Sun Pharmaceutical Industries Limited, and Sun Pharmaceutical Industries, Inc. (collectively, “Sun” or “Defendants”) identify the following issues of law that remain to be litigated, including citations to the authorities upon which Sun relies. The following statements are not exhaustive, and Sun reserves the right to prove any matters identified in its pleadings, interrogatory responses, and/or expert reports. In addition, the citation of authorities referenced in this document is not intended to be exhaustive. Defendants reserve the right to rely on additional authorities in support of their defenses and intended proofs. Defendants also reserve the right to rely upon the legal authorities cited by Plaintiffs in their corresponding exhibit. Sun intends to offer evidence as to the issues of fact and issues of law identified in this pretrial order. Sun reserves the right to modify or amend this Statement to the extent necessary to reflect any future rulings by the Court and to supplement or amend this Statement to fairly respond to any new issues that Wyeth LLC, Wyeth Pharmaceuticals LLC, PF Prism C.V., PBG Puerto Rico LLC, and PF Prism IMB B.V. (collectively, “Plaintiffs”) may raise. To the extent that Sun’s Statement of Issues of Fact that Remain to be Litigated, which is submitted as Exhibit 3, contains issues of law, those issues are incorporated herein by reference. Moreover, if any issue of law identified below should properly be considered an issue of fact, then such statement shall be considered to be part of Sun’s Statement of Issues of Fact That Remain to be Litigated. Sun incorporates by reference its expert reports in support of any proof to be presented by expert testimony.

I. PATENTS-IN-SUIT

Plaintiffs allege Sun’s submission of ANDA No. 209577 requesting approval to sell generic 100 mg and 500 mg bosutinib tablets (“Sun’s ANDA Products”) infringes claim 7 of the ’148 patent, claim 1 of U.S. Patent No. 7,919,625 (“the ’625 patent”), and claims 2 and 3 of U.S.

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Patent No. 7,776,678 (“the ’678 patent”).

II. NON-INFRINGEMENT

A. Issues of Law to be Litigated

- i. Whether Plaintiffs have proven by a preponderance of the evidence that the administration of Sun’s ANDA Products would directly, literally infringe claim 7 of the ’148 patent.
- ii. Whether Plaintiffs have proven by a preponderance of the evidence that Sun will knowingly induce infringement of claim 7 of the ’148 patent.
- iii. Whether Plaintiffs have proven by a preponderance of the evidence that Sun will contribute to the infringement of claim 7 of the ’148 patent.
- iv. Whether Plaintiffs have proven by a preponderance of the evidence that the administration of Sun’s ANDA Product would directly, literally infringe claim 1 of the ’625 patent.
- v. Whether Plaintiffs have proven by a preponderance of the evidence that the Sun’s ANDA Product would directly, literally infringe claims 2 and 3 of the ’678 patent.

B. Legal Authority

The patentee bears the sole burden of proving by a preponderance of the evidence that the accused product “includes every limitation of the claim or an equivalent of each limitation.” *Dolly, Inc. v. Spalding & Evenflo Companies, Inc.*, 16 F.3d 394, 397 (Fed. Cir. 1994). There are two types of infringement: (1) direct infringement under 35 U.S.C. § 271(a), and (2) indirect infringement, which encompasses induced infringement under 35 U.S.C. § 271(b) and contributory infringement under 35 U.S.C. § 271(c).

EXHIBIT 51. **Direct Infringement**

Under 35 U.S.C. § 271(a), “whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore, infringes the patent.” Infringement under Section 271(a) is typically referred to as “direct infringement.” Direct infringement may be either literal or under the doctrine of the equivalents.

Direct infringement of a method claim requires that a single party carry out, or at least control, all acts alleged to constitute infringement. *See Voter Verified, Inc. v. Premier Election Solutions, Inc.*, 698 F.3d 1374, 1383-84 (Fed. Cir. 2012).

The determination of whether an accused product or method directly infringes a patent claim has two steps: (1) construction of the claim to determine its meaning and scope and (2) comparison of the properly construed claim to the product or method at issue. *See Tanabe Seiyaku Co., Ltd. v. U.S. Int’l Trade Comm’n*, 109 F.3d 726, 731 (Fed. Cir. 1997) (citing *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff’d* 517 U.S. 370 (1996)).

The first step of the infringement analysis is determining the meaning and scope of the claims, *see ActiveVideo Networks, Inc. v. Verizon Comm’cns, Inc.*, 694 F.3d 1312, 1319 (Fed. Cir. 2012), which this Court did in its February 17, 2017, Memorandum Order (D.I. 290). Claims should not be interpreted such that “proof of infringement would necessitate forward-looking assessments” as to whether the present acts of the alleged infringer may at some point in the future meet the limitations of the claims as construed. *Medicines Co. v. Mylan, Inc.*, 853 F.3d 1296, 1303 (Fed. Cir. 2017).

The second step is to compare the claims as construed to the accused device to determine

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whether the claims read onto the accused product. *ActiveVideo Networks, Inc.*, 694 F.3d at 1319. The first step is a question of law, while the second step is a question of fact. *Id.* “To prove infringement, a plaintiff must prove the presence of each and every claim element or its equivalent in the accused method or device.” *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 655 F.3d 1364, 1378 (Fed. Cir. 2011). If “even one claim limitation is missing or not met, there is no literal infringement.” *MicroStrategy Inc. v. Bus. Objects, S.A.*, 429 F.3d 1344, 1352 (Fed. Cir. 2005).

2. **Indirect Infringement**

There can be no indirect infringement without an act of direct infringement. *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 774 (Fed. Cir. 1993). Thus, absent direct infringement of the patent claims, there can be no inducement of infringement and no contributory infringement. *Id.* (“Liability for either active inducement of infringement or for contributory infringement is dependent upon the existence of direct infringement.”).

a) ***Induced Infringement***

Induced infringement under 35 U.S.C. § 271(b) requires evidence “that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another’s infringement.” *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en banc) (quoting *MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp.*, 420 F.3d 1369, 1378 (Fed. Cir. 2005)). To induce infringement, the accused infringer’s actions must have caused the infringement. *Power Integrations, Inc. v. Fairchild Semiconductor Int’l, Inc.*, 843 F.3d 1315, 1331-32 (Fed. Cir. 2016). Further, “in an action for induced infringement, it is necessary for the plaintiff to show that the alleged inducer knew ... the induced acts were infringing.” *Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920, 1925 (2015).

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A patent owner must prove that an accused infringer has a specific intent and is taking action to induce infringement. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003). The intent requirement for inducement requires the inducer to “have an affirmative intent to cause direct infringement.” *DSU Med.*, 471 F.3d at 1306. Mere knowledge of infringement is insufficient: the alleged infringer must have actually induced infringement. *Power Integrations*, 843 F.3d at 1331 (“[A] finding of induced infringement requires actual inducement.”). Intent cannot be inferred: “[W]here a product has substantial noninfringing uses, intent to induce infringement cannot be inferred even when [the accused infringer] has actual knowledge that some users of its product may be infringing the patent.” *Warner-Lambert*, 316 F.3d at 1365; *see also Takeda Pharm. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015) (explaining that the accused infringer’s mere knowledge of infringing “off-label” uses was not sufficient under the general principles of inducement liability).

“[L]iability for induced infringement under § 271(b) must be predicated on direct infringement. *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357, 1364 (Fed. Cir. 2017) (quoting *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 572 U.S. 915, 920 (2014)) (internal quotation marks omitted). When there is “no single actor performs all steps of a method claim, direct infringement only occurs if the acts of one are attributable to the other such that a single entity is responsible for the infringement.” *Eli Lilly*, 845 F.3d at 1364 (quoting *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1022 (Fed. Cir. 2015)) (internal quotation marks omitted). “The performance of method steps is attributable to a single entity in two types of circumstances: when that entity directs or controls others’ performance, or when the actors form a joint enterprise.” *Eli Lilly*, 845 F.3d at 1364 (quoting *Akamai Techs.*, 797 F.3d at 1022) (internal quotation marks omitted).

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Induced infringement premises liability upon “purposeful, culpable expression and conduct” and “active steps” taken to encourage direct infringement. *DSU Med.*, 471 F.3d at 1305-06 (quoting *Metro-Goldwyn-Mayer Studios Inc. v. Gorkster, Ltd.*, 125 S.Ct. 2764, 2779-80 (2005)); see also *Novartis Pharm., Corp. v. Wockhardt USA LLC*, 2013 WL 5770539, at *9 (D.N.J. Oct. 23, 2013). “[T]he general rule is that inducement of infringement under § 271(b) does not lie when the acts of inducement occurred before there existed a patent to be infringed.” *Nat’l Presto Indus., Inc. v. West Bend Co.*, 76 F.3d 1185, 1196 (Fed. Cir. 1996).

For allegations of inducement based on a label of a prescription drug, “[t]he label must encourage, recommend, or promote infringement.” *Takeda*, 785 F.3d at 631. Where the label is silent on a required element, there is no induced infringement. See *Mallinckrodt Hosp. Prod. IP Ltd. v. Praxair Distribution, Inc.*, No. CV 15-170-GMS, 2017 WL 3867649, at *26 (D. Del. Sept. 5, 2017) (finding no infringement where the “label [did] not require or recommend” a required element of the claims).

Warnings within a drug’s label are not proof of intent to induce. *Shire LLC v. Amneal Pharm. LLC*, 2014 WL 2861430, at *3-6 (D.N.J. 2014), *rev’d in part on other grounds by* 802 F.3d 1301 (Fed. Cir. 2015); *Otsuka Pharm. Co., Ltd. v. Torrent Pharm. Ltd., Inc.*, 99 F. Supp. 3d 461, 490-95 (D.N.J. 2015); see also, e.g., *United Therapeutics Corp. v. Sandoz, Inc.*, 2014 WL 4259153, at *18 (D.N.J. Aug. 29, 2014) (“[T]he warnings in Sandoz’s label do not amount to an implicit instruction.”). “[I]f a patentee must engage in a ‘scholarly scavenger hunt’ through the label to identify statements that may inferentially but not inevitably tie to a physician’s thoughts or acts, the inducement theory necessarily fails.” *Otsuka Pharm. Co.*, 99 F. Supp. 3d at 493 (citing *United Therapeutics Corp.*, 2014 WL 4259153, at *19); see also *Takeda*, 785 F.3d at 631; *Acorda Therapeutics, Inc. v. Apotex Inc.*, 2011 WL 4074116, at *17-*20 (D.N.J. Sept 6, 2011).

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There is no obligation on defendants to diminish the risk of infringement, and imposing such an obligation improperly shifts a burden on defendants. *See Takeda*, 785 F.3d at 632 n.4 (finding that imposing an obligation on defendants to take “affirmative steps to make sure others avoid infringement” would “turn[]the legal [infringement] test on its head”).

Inducement under a theory of willful blindness requires “(1) the defendant must subjectively believe that there is a high probability that a fact exists and (2) the defendant must take deliberate actions to avoid learning of that fact.” *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 769 (2011). Willful blindness requires more than a “merely a ‘known risk’ that the induced acts are infringing.” *Id.* at 770. Willful blindness also requires “active efforts by an inducer to avoid knowing about the infringing nature of the activities.” *Id.*

b) Contributory Infringement

Contributory infringement under 35 U.S.C. § 271(c) requires evidence that “[w]hoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus or use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use.

To plead a claim of contributory infringement, a plaintiff “must aver an alleged infringer (1) offered to sell, sells, or imports, (2) a material part of an [sic] patented invention, (3) knew of the patented invention, (4) knew the part was made for, or adapted to use, in a patented invention, and (5) the part has no substantial noninfringing use.” *Hand Held Prods., Inc. v. Amazon.com, Inc.*, C.A. No. 12-768-RGA-MPT, 2013 WL 507149, at *3 (D. Del. Feb 6, 2013); *see also In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1337

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(Fed. Cir. 2012); *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1312 (Fed. Cir. 2005). “It is axiomatic that ‘[t]here can be no inducement or contributory infringement without an underlying act of direct infringement.’” *Nalco Company v. Chem-Mod, LLC*, 883 F.3d 1337, 1355 (Fed. Cir. 2018) (citing *Bill of Lading*, 681 F.3d at 1333). A patent owner must prove that the accused infringer “knew that the combination for which his component was especially designed was both patented and infringing.” *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 488 (1964); *see also Global Tech Appliances*, 563 U.S. at 763-764. Contributory infringement requires knowledge that the component was especially designed for use in a combination that was patented and infringing, not intent that it be used as such. *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469 (Fed. Cir. 1990).

The use of staple articles of commerce does not give rise to contributory infringement. *See, e.g., Ricoh Co., Ltd. v. Quanta Computer Inc.*, 550 F.3d 1325, 1338 (Fed. Cir. 2008) (“the [Supreme Court] explained that the staple article of commerce doctrine codified in § 271(c) ‘was devised to identify instances in which it may be presumed from distribution of an article in commerce that the distributor intended the article to be used to infringe another's patent, and so may justly be held liable for that infringement.’”) (citations omitted).

A substantial non-infringing use is any use that is “not unusual, farfetched, illusory, impractical, occasional, aberrant, or experimental.” *Bill of Lading*, 681 F.3d at 1337 (quoting *Vita-Mix Corp. v. Basic Holdings, Inc.*, 581 F.3d 1317, 1327-29 (Fed. Cir. 2009)). “For purposes of contributory infringement, the inquiry focuses on whether the accused products can be used for purposes *other than* infringement.” *Bill of Lading*, 681 F.3d at 1338 (emphasis original). “The burden is on the Plaintiffs to prove that there is not a substantial noninfringing use”

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Vanda Pharms., Inc. v. Roxane Labs., Inc., 203 F. Supp. 3d 412, 432 (D. Del. 2016).

III. INVALIDITY

A. Issues of Law to be Litigated

- i. Whether Plaintiffs have proven by a preponderance of the evidence that the '148 patent and the '625 patent are entitled to priority dates prior to November 6, 2003.
- ii. Whether Plaintiffs have proven by a preponderance of the evidence that the '148 patent and the '625 patent are entitled to invention dates prior to November 6, 2002, or, alternatively, prior to December 6, 2002.
- iii. Whether Sun has proven by clear and convincing evidence that claim 1 of the '625 patent is invalid as anticipated by the prior art pursuant to 35 U.S.C. § 102.
- iv. Whether Sun has proven by clear and convincing evidence that claims 2 and 3 of the '678 patent are invalid as anticipated by the prior art pursuant to 35 U.S.C. § 102.
- v. Whether Sun has proven by clear and convincing evidence that claim 1 of the '625 patent is invalid as obvious in view of the prior art pursuant to 35 U.S.C. § 103.
- vi. Whether Sun has proven by clear and convincing evidence that claims 2 and 3 of the '678 patent are invalid as obvious in view of the prior art pursuant to 35 U.S.C. § 103.
- vii. Whether Sun has proven by clear and convincing evidence that claim 7 of the '148 patent is invalid as obvious in view of the prior art pursuant to 35 U.S.C.

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§ 103.

- viii. Whether Sun has proven by clear and convincing evidence that claims 2 and 3 of the '678 patent are invalid in view of the '148 patent pursuant to the doctrine of obviousness-type double patenting.
- ix. Whether Sun has proven by clear and convincing evidence that claim 1 of the '625 patent is invalid as not enabled pursuant to 35 U.S.C. § 112.
- x. Whether Sun has proven by clear and convincing evidence that claims 2 and 3 of the '678 patent are invalid as not enabled pursuant to 35 U.S.C. § 112.
- xi. Whether Sun has proven by clear and convincing evidence that claim 7 of the '148 patent is invalid as not enabled pursuant to 35 U.S.C. § 112.
- xii. Whether Sun has proven by clear and convincing evidence that claim 1 of the '625 patent is invalid for lack of written description pursuant to 35 U.S.C. § 112.
- xiii. Whether Sun has proven by clear and convincing evidence that claim 7 of the '148 patent is invalid for lack of written description pursuant to 35 U.S.C. § 112.
- xiv. Whether Sun has proven by clear and convincing evidence that claim 1 of the '625 patent is invalid as indefinite pursuant to 35 U.S.C. § 112.
- xv. Whether Sun has proven by clear and convincing evidence that claims 2 and 3 of the '678 patent are invalid as indefinite pursuant to 35 U.S.C. § 112.

B. Legal Authority

- 1. Pre-AIA Law Applies

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The effective filing dates of all the asserted claims of the Patent-in-Suit are prior to March 16, 2013. Thus, the asserted patents are subject to pre-AIA 35 U.S.C. § 101 *et seq.*

2. **Date of Invention**

Under pre-AIA section 102(g), a patent owner may prove seek to prove an earlier conception and reasonable diligence in reduction to practice in order to antedate a reference. *Perfect Surgical Techniques, Inc. v. Olympus America, Inc.*, 841 F.3d 1004, 1007 (Fed. Cir. 2016). “Reasonable diligence must be shown throughout the entire critical period, which begins just prior to the competing reference’s effective date and ends on the date of the invention’s reduction to practice.” *Id.*

The question of reasonable diligence is one of fact. *Brown v. Barbacid*, 436 F.3d 1376, 1379 (Fed. Cir. 2006). “To establish diligence in reduction to practice, the basic inquiry is whether . . . there was reasonably continuing activity to reduce the invention to practice... And, the inventor must not abandon, suppress, or conceal the invention after he or she reduces it to practice... The filing of a patent application is constructive reduction to practice of the invention disclosed therein, and failing to file such an application within a reasonable time after first making the invention may constitute such abandonment, suppression, or concealment.” *Tyco Healthcare Group LP v. Ethicon Endo-Surgery, Inc.*, 774 F.3d 968, 975 (Fed. Cir. 2014) (internal quotations omitted).

3. **The Presumption Of Validity**

The claims of an issued patent are presumed valid, and Defendants have the burden to prove that each claim is invalid by “clear and convincing evidence.” *Microsoft Corp. v. i4i Ltd. P’Ship*, 564 U.S. 91, 95 (2011); *see also* 35 U.S.C. § 282(a). “[I]f the PTO did not have all material facts before it, its considered judgment may lose significant force.” *Id.* at 111. A court

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is not bound by the events in the PTO or by the PTO's decisions made during prosecution of a patent. *See Panduit Corp. v. Dennison Mfg. Co.*, 774 F.2d 1082, 1096 (Fed. Cir. 1985), *vacated on other grounds*, 475 U.S. 809 (1986). Accordingly, the burden of proving invalidity by clear and convincing evidence may still be carried when the prior art was before the PTO. *See Celeritas Techs. Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1360-61 (Fed. Cir. 1998) (invalidating claims in view of an article that disclosed each of the claimed limitations, even though the anticipating article had been considered by the PTO and the patent allowed in view of the article); *see also Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1259-1260 (Fed. Cir. 2012); *Surface Tech., Inc. v. U.S. Int'l Trade Comm'n*, 801 F.2d 1336, 1340-41 (Fed. Cir. 1986); *Pharmastem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1366-67 (Fed. Cir. 2007). "Whether a reference was previously considered by the PTO, the burden is the same: clear and convincing evidence of invalidity." *Sciele*, 684 F.3d at 1260 (citation omitted). "In short, there is no heightened or added burden that applies to invalidity defenses that are based upon references that were before the Patent Office." *Id.*

C. Anticipation

A person is not entitled to a patent if the invention claimed was "described in a printed publication ... more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b) (pre-AIA). "Anticipation is a question of fact, but validity is a question of law." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1377 (Fed. Cir. 2007); *see also In re NTP, Inc.*, 654 F.3d 1279, 1301 (Fed. Cir. 2011) ("Although anticipation is a question of fact, whether a prior art reference is enabling is a question of law with underlying factual inquiries." (citation omitted)).

A claim is anticipated when a prior art reference discloses each and every claim

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limitation, either explicitly or inherently, of the claimed invention. *In re Paulsen*, 30 F.3d 1475, 1478-79 (Fed. Cir. 1994); *see Akamai Techs., Inc. v. Cable & Wireless Internet Servs., Inc.*, 344 F.3d 1186, 1192, 1192-93 (Fed. Cir. 2003). So long as the claim limitation at issue “is within the knowledge of a skilled artisan,” a reference anticipates “even if it does not specifically disclose” the claim limitation. *In re Graves*, 69 F.3d 1147, 1152 (Fed. Cir. 1995); *cf. Forest Labs., Inc. v. Ivax Pharms., Inc.*, 501 F.3d 1263, 1268 (Fed. Cir. 2007) (stating that, “[b]ecause a racemate does encompass its two enantiomers,” the disclosure of the racemate in the prior art “in effect does state that there is [the] enantiomer,” but nevertheless finding no anticipation because the prior art “d[id] not enable the preparation of the [enantiomer]”). Thus, “a prior art reference must be ‘considered together with the knowledge of one of ordinary skill in the pertinent art’ at the time the ... patent was filed.” *In re Paulsen*, 30 F.3d at 1480 (quoting *In re Samour*, 571 F.2d 559, 562 (C.C.P.A. 1978)); *In re Samour*, 571 F.2d at 563 (“The critical issue ... is whether the claimed subject matter was in possession of the public more than one year prior to applicant’s filing date[,], not whether the evidence showing such possession came before or after the date of the primary reference.”).

“[A]nticipation does not require actual performance of suggestions in a disclosure,” but rather requires only those suggestions be enabling to one of skill in the art. *Novo Nordisk Pharms. v. Bio-Tech. Gen.*, 424 F.3d 1347, 1355 (Fed. Cir. 2005); *accord Impax Labs., Inc. v. Aventis Pharms., Inc.*, 468 F.3d 1366, 1381-82 (Fed. Cir. 2006); *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985); *In re Montgomery*, 677 F.3d 1375, 1382 (Fed. Cir. 2012) (noting that even if disclosed clinical trial protocol “merely proposed the administration” of the claimed drug, “it would still anticipate”). “The standard for what constitutes proper enablement of a prior art reference for purposes of anticipation under section 102, however, differs from the enablement

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standard under section 112.” *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1325 (Fed. Cir. 2005). For example, “proof of efficacy is not required in order for a reference to be enabled for purposes of anticipation.” *Id.* at 1326; *accord In re Gleave*, 560 F.3d 1331, 1334-35 (Fed. Cir. 2009) (a prior art reference need not “demonstrate the invention’s utility”); *see also GlaxoSmithKline LLC v. Teva Pharmaceuticals USA Inc.*, Civil Action No. 14-878-LPS-CJB, D.I. 346 (Report and Recommendation) at 40-42 (D. Del. May 2, 2017) (“R&R”). Moreover, “a disclosure lacking a teaching of how to use a fully disclosed compound for a specific, substantial utility or of how to use for such purpose a compound produced by a fully disclosed process is... entirely adequate to anticipate a claim to either the product or the process and, at the same time, entirely inadequate to support the allowance of such a claim.” *In re Hafner*, 410 F.2d 1403, 1405 (C.C.P.A. 1969). Other references may be used to prove that the single prior art reference contained an enabling disclosure, to explain the meaning of a term in a prior art reference, or to show that a characteristic not disclosed in a prior art reference is inherent. *See, e.g., Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1379 (Fed. Cir. 2001) (“Enablement of an anticipatory reference may be demonstrated by a later reference.”); *see generally* U.S. Patent and Trademark Office Manual of Patent Examining Procedure (“M.P.E.P.”) § 2131.01.

A prior art reference can anticipate a claim if the prior art discloses all of the claimed elements arranged or combined in the same way as in the claim. *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015). Anticipation does not require that the prior art reference use exactly the same wording as the challenged claim. *See In re Gleave*, 560 F.3d at 1334. The Federal Circuit has explained that although references cannot be combined for purposes of anticipation, additional references may be used to interpret the allegedly anticipating reference and shed light on what it would have meant to those skilled in the art at the time of

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invention. *See Continental Can Co., U.S.A. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991). However, “[s]uch evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.” *Id.*

The disclosure of a genus in a prior art reference anticipates a later claim to a species within that genus if a skilled artisan could “at once envisage each member” of the genus or a more limited class within the genus described by the reference. *In re Petering*, 301 F.2d 676, 681 (C.C.P.A. 1962). “Thus, species are unpatentable when prior art disclosures describe the genus containing those species such that a person of ordinary skill in the art would be able to envision every member of the class.” *Abbvie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Trust*, 764 F.3d 1366, 1379 (Fed. Cir. 2014); *see also Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356, 1361 (Fed. Cir. 2012) (“[T]he issue of anticipation turns on whether the genus was of such a defined and limited class that one of ordinary skill in the art could ‘at once envisage’ each member of the genus.”).

A claim is inherently anticipated if the prior art necessarily functions in accordance with or includes the claimed limitations. *MEHL/Biophile Intern. Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999); *see also Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003) (“[A] prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference.”); R&R at 22-24. “Thus, a prior art reference without express reference to a claim limitation may nonetheless anticipate by inherency.” *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1375-76 (Fed. Cir. 2005). “[I]nherency is not necessarily coterminous with knowledge of those of ordinary skill in the art. *Id.* at 1347 (quoting *In re Cruciferous Sprout*

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Litig., 301 F.3d 1343, 1349 (Fed. Cir. 2002)). “Inherent anticipation does not require an appreciation of the inherent limitation by those of skill in the art before the critical date of the patents at issue.” *Prima Tek II, L.L.C. v. Polypap, S.A.R.L.*, 412 F.3d 1284, 1289-90 (Fed. Cir. 2005). “[D]iscovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer.” *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999).

“Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent.” *Bristol-Myers*, 246 F.3d at 1376; *see also In re May*, 574 F.2d 1082, 1090 (C.C.P.A. 1978); *Akamai*, 344 F.3d at 1192, 1194-95; *see also In re Cruciferous Sprout Litig.*, 301 F.3d at 1349-51, 1352 & n.4 (finding that a claim was anticipated because the only new limitation over the prior art was inherently present in the prior art); *In re Montgomery*, 677 F.3d at 1380-81 (finding publication of protocol of clinical trial inherently anticipates claim directed to method of treatment). Indeed, if there are no actual differences between the claimed methods and ones disclosed in the prior art except the ***intended*** results of practicing those methods, then practicing the prior art methods necessarily achieves the intended results of the claimed methods. *See Cubist Pharms., Inc. v. Hospira, Inc.*, 75 F. Supp. 3d 641, 660 (D. Del. 2014) (finding that following the steps of the suggestion for future study disclosed in the prior art reference would “have the physiological effect of minimizing skeletal muscle toxicity” which was the claim limitation that was not expressly disclosed in the reference, and concluding that, since “minimizing skeletal muscle toxicity was a necessary accompaniment to the other disclosed claimed limitations [it was] therefore [] inherently disclosed” by the prior art reference). In cases where the inherent property corresponds to a claimed new benefit of the

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prior art, the new realization alone does not render the invention patentable. *Perricone*, 432 F.3d at 1377-78.

To determine whether a use is “new,” courts compare the actual steps of the patent with the method in the prior art reference. See *Bristol-Myers*, 246 F.3d at 1375-76; *Wedeco UV Techs. v. Calgon Carbon*, Civil Action No. 01-924 (JAG), 2006 WL 1867201, *14-*15 (D.N.J. June 30, 2006) (“[I]n comparing the process of the invention with that in the prior art, the *BMS* court looked for an identity of physical steps.”). The key is whether the patent teaches a “manipulative difference in the steps of the claim.” *Bristol-Myers*, 246 F.3d at 1376. That is, district courts undertaking an inherent anticipation inquiry focus on whether the allegedly new method requires a different physical step when practicing the claimed method than those methods disclosed in the prior art. See, e.g., *Aventis Pharms. Inc. v. Barr Labs., Inc.*, 411 F. Supp. 2d 490, 523 (D.N.J. 2006) (noting that “in comparing the process of the invention with that in the prior art the [*Bristol-Myers Squibb*] [C]ourt looked for an identify of physical steps” and “[a]pplying this approach to the present case, the new method and the old method have an identity of physical steps” and “the fact that the [] process [in the asserted patent] is associated with a new intended result [administration of a drug while avoiding certain cardiac events] does not render it patentably new”); cf. *Innovatit Seafood Sys. LLC v. Comm’r for Patents*, 573 F. Supp. 2d 96, 98 (D.D.C. 2008) (concluding that “the application of [an] old process [subjecting shellfish to high pressure] to [a] new purpose [pasteurizing the shellfish], *without any meaningful change in the procedure*, is [not] patentable over” a prior art reference that taught the same process for a different purpose, shucking shellfish (emphasis added)).

Moreover, adding a limitation requiring contemporaneous recognition of the purported benefit cannot save the validity of the claims. *Geneva*, 339 F.3d at 1377 (“At the outset, this

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court rejects the contention that inherent anticipation requires recognition in the prior art.”); *Bristol-Myers*, 246 F.3d at 1374-76; *In re Cruciferous Sprout*, 301 F.3d at 1350-51. Indeed, simply adding an “intent” limitation to a claim in which there is no other manipulative difference between the physical steps of the methods disclosed in the invention and the prior art cannot rescue claims from inherent anticipation. *See Perricone*, 432 F.3d at 1371, 1378 & n.*; *see also* R&R at 23-26, 36-37 (“[T]o determine whether a use is ‘new,’ courts compare the actual steps of the patent with the method in the prior art reference and they assess whether there is a manipulative difference in the steps of the method... [T]he Court is not persuaded that simply adding an ‘intent’ limitation to the claim successfully avoids the doctrine of inherent anticipation.”) (quotes omitted).

D. Obviousness

A claimed invention is obvious “if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.” 35 U.S.C. § 103 (2006). Obviousness is a question of law based on underlying facts including: (1) the scope and content of the prior art, (2) the level of ordinary skill in the pertinent art, (3) the differences between the prior art and the claims at issue, and (4) secondary considerations. *Prometheus Labs., Inc. v. Roxane Labs., Inc.*, 805 F.3d 1092, 1097-98 (Fed. Cir. 2015); *Bayer Schering Pharma AG v. Barr Labs., Inc.*, 575 F.3d 1341, 1346-47 (Fed. Cir. 2009); *Merck Sharp & Dohme B.V. v. Warner Chilcott Co., LLC*, 2016 WL 4497054, at *8 (D. Del. Aug, 26, 2016). Based on these factual inquiries, the Court must determine, as a matter of law, whether or not the claimed subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the alleged invention was made. *See Graham v. John Deere Co.*, 383 U.S. 1, 17-18

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(1966); *see also KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 406 (2007). “[A]dvances that would occur in the ordinary course without real innovation” are not deserving of a patent. *KSR*, 550 U.S. at 419, 426-27.

The clear and convincing evidence standard for the obviousness determination does not apply to the “ultimate legal conclusion of obviousness itself,” but only to the disputed facts underlying the conclusion of obviousness. *Newell Cos., Inc. v. Kenney Mfg. Co.*, 864 F.2d 757, 767 (Fed. Cir. 1988); *see also i4i Ltd. P’ship*, 564 U.S. at 95, 114 (2011).

The Supreme Court has “set forth an expansive and flexible approach” to obviousness. *KSR*, 550 U.S. at 415. The Supreme Court has emphasized that an obviousness analysis “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *Id.* at 418. The Federal Circuit has stated that it “cannot, in the face of *KSR*, cling to formalistic rules for obviousness, customize its legal tests for specific scientific fields in ways that deem entire classes of prior art teachings irrelevant, or discount the significant abilities of artisans of ordinary skill in an advanced area of art.” *In re Kubin*, 561 F.3d 1351, 1360-61 (Fed. Cir. 2009) (citing *In re Durden*, 763 F.2d 1406, 1411 (Fed. Cir. 1985)).

“‘[I]nherency may supply a missing claim limitation in an obviousness analysis.’” *Millennium Pharms., Inc. v. Sandoz Inc.*, 2015 WL 4966438, at *8 (D. Del. Aug. 20, 2015) (quoting *Par Pharm., Inc. v. TWI Pharm., Inc.*, 773 F.3d 1186, 1194-95 (Fed. Cir. 2014)). An element is inherent for purposes of the obviousness analysis “‘when the limitation at issue is the “natural result” of the combination of prior art elements.’” *Id.* (quoting *Par*, 773 F.3d at 1995); *see also In re Huai-Hung Kao*, 639 F.3d 1057, 1070 (Fed. Cir. 2011) (finding that a “claimed ‘food effect’ [wa]s an inherent property” of the formulation covered by the asserted patent such

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that that the claim element “add[ed] nothing of patentable consequence,” and affirming obviousness where prior art reference did not teach the inherent element).

“[W]here there is a range disclosed in the prior art, and the claimed invention falls within that range, there is a presumption of obviousness.” *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1322 (Fed. Cir. 2004). That presumption can only be rebutted if the patentee can show that (1) the prior art taught away from the claimed invention, (2) that the claimed range achieves unexpected results, or (3) there are other pertinent secondary considerations. *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 738 (Fed. Cir. 2013).

A claim may be proven obvious in view of a single prior art reference or in view of a combination of prior art references. When the prior art references are combined to invalidate a claim under 35 U.S.C. § 103, there must be some reason in the prior art to do so. That reason need not be expressly stated in one or all of the references used to show obviousness, but rather “may be found in any number of sources, including common knowledge, the prior art as a whole, or the nature of the problem itself.” *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1361 (Fed. Cir. 2006); *see also Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1291 (Fed. Cir. 2006).

“In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls.” *KSR*, 550 U.S. at 419; *see also In re Beattie*, 974 F.2d 1309, 1311-12 (Fed. Cir. 1992). “The question is not whether the combination was obvious to the patentee but whether the combination was obvious to a person with ordinary skill in the art.” *KSR*, 550 U.S. at 420. “Under the correct analysis, any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.” *Id.*

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“As the Supreme Court explained, ‘The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.’ The Supreme Court went on to state that ‘when a patent simply arranges old elements with each *performing* the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious.’” *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1326 (Fed. Cir. 2009) (emphasis original) (citations and internal quotation marks omitted) (quoting *KSR*, 550 U.S. at 417).

Obviousness also requires a reasonable expectation of success in practicing the claimed subject matter, but that expectation need not be absolute. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007). “[O]bviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success.” *Id.* at 1364; *see also In re O’Farrell*, 853 F.2d 894, 904 (Fed. Cir. 1988) (“For obviousness under § 103, all that is required is a reasonable expectation of success.”); *Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286, 1292 (Fed. Cir. 2013). Furthermore, for pharmaceutical products and methods of treatment, a reasonable expectation of success does not require large clinical trials—studies on small numbers of patients can be sufficient. *See, e.g., Acorda Therapeutics, Inc. v. Roxane Labs., Inc.*, 2017 WL 1199767, at *22-23 (D. Del. Mar. 31, 2017) (finding that “a POSA would have had a reasonable expectation that [the molecule at issue] would be ‘therapeutically effective,’” based on studies “conducted in small numbers of patients,” not randomized, and not double-blinded because “the prior art need not contain ‘[c]onclusive proof of efficacy’” (citation omitted)).

1. Scope and Content of the Prior Art

The scope of the prior art includes art which is “reasonably pertinent to the particular

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problem with which the inventor was involved.” *In re GPAC Inc.*, 57 F.3d 1573, 1577 (Fed. Cir. 1995) (citation omitted). In determining whether the claimed invention falls within the scope of the relevant prior art, a court first examines, “the field of the inventor’s endeavor” and “the particular problem with which the inventor was involved” at the time the invention was made. *Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.*, 411 F.3d 1332, 1339 (Fed. Cir. 2005) (citation omitted). “A reference is reasonably pertinent if, even though it may be in a different field of endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor’s attention in considering his problem.” *Id.* (citation omitted).

Printed publications, patents, and patent applications all constitute prior art under 35 U.S.C. § 102. Specifically, art is prior art under § 102(a) if it was “patented” or “described in a printed publication ... before the effective filing date of the claimed invention.” 35 U.S.C. § 102(a); *accord Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1577 (Fed. Cir. 1996) (“[U]nder section 102(a), a document is prior art only when published before the invention date.”). Art is prior art under § 102(b) if it was “patented or described in a printed publication ... one year prior to the date of the application for patent in the United States.” 35 U.S.C. § 102(b) (pre-AIA).

Prior art references need not provide enabling disclosure. *See ABT Sys., LLC v. Emerson Elec. Co.*, 797 F.3d 1350, 1360 n.2 (Fed. Cir. 2015); *Geo. M. Martin, Co. v. Alliance Mach. Sys. Int’l, LLC*, 618 F.3d 1294, 1302-03 (Fed. Cir. 2010); *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1289, 1297 (Fed. Cir. 2010), *reh’g en banc granted on inequitable conduct, opinion vacated*, 374 F. App’x 35 (Fed. Cir. 2010), *and opinion reinstated in part*, 649 F.3d 1276 (Fed. Cir. 2011) (“In order to render a claimed apparatus or method obvious, the cited prior art as a whole must enable one skilled in the art to make and use the apparatus or method. An individual prior art reference, on the other hand, need not be enabled; it qualifies as a prior art,

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regardless, for whatever is disclosed therein.” (citation and quote omitted)).

2. Level of Ordinary Skill in the Art

The person of ordinary skill in the art is a hypothetical person presumed to know all of the teachings of the prior art references in the field of the invention at the time the invention was made. *See Union Carbide Corp. v. Am. Can Co.*, 724 F.2d 1567, 1576 (Fed. Cir. 1984).

In determining the level of ordinary skill in the art, a court should consider the following factors: “(1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field.” *Daiichi Sankyo Co., Ltd. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007). However, “[n]ot all [of the factors listed above] may be present in every case, and one or more of these or other factors may predominate in a particular case.” *Imperial Chem. Indus., PLC v. Danbury Pharmacal, Inc.*, 777 F. Supp. 330, 371 (D. Del. 1991) (citing *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696-97 (Fed. Cir. 1983)). The actual inventor’s skill or knowledge is not relevant. *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985).

3. Differences Between the Claimed Invention and the Prior Art

In determining the differences between the claimed invention and the prior art, obviousness is judged under “an expansive and flexible approach” driven by “common sense.” *KSR*, 550 U.S. at 401, 403; *accord Senju Pharm. Co. Ltd. v. Apotex Inc.*, 836 F. Supp. 2d 196, 208 (D. Del. 2011) (“The Supreme Court has emphasized the need for courts to value ‘common sense’ over ‘rigid preventative rules’....”) (citation omitted). In making this determination, the court must consider both the claimed invention and the prior art as a whole in light of the court’s construction of the claims at issue. *See Kahn v. Gen. Motors Corp.*, 135 F.3d 1472, 1479-80

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(Fed. Cir. 1998) (“In determining obviousness, the invention must be considered as a whole and the claims must be considered in their entirety.”).

“While it may be easier to prove obviousness if each limitation of the claimed invention is found in the prior art, the level of skill of one of ordinary skill in the art can, at times, fill in the gap when limitations of the claimed invention are not specifically found in the prior art.” *Belden Techs., Inc. v. Superior Essex Commc’ns LP*, 802 F. Supp. 2d 555, 563 (D. Del. 2011).

A conclusion of obviousness may be based on a single reference or a combination of prior art references. *See Senju Pharm.*, 836 F. Supp. 2d at 208 (“[A] defendant asserting obviousness in view of a combination of references has the burden to show that a person of ordinary skill in the relevant field had a reason to combine the elements in the manner claimed.”); *see also In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) (“We see no clear error in the Board’s determination as to the teachings of the prior art references, in combination.”). Where the issue of obviousness is based on a combination of elements, a patent challenger must demonstrate “that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention.” *Pfizer*, 480 F.3d at 1361.

“The combination of familiar elements according to known methods is *likely* to be obvious when it does no more than yield predictable results.” *KSR*, 550 U.S. at 416 (emphasis added); *Q.I. Press Controls, B.V. v. Lee*, 752 F.3d 1371, 1379 (Fed. Cir. 2014) (quoting *KSR*). This is because “[g]ranting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility.” *KSR*, 550 U.S. at 402.

“[O]bviousness exists when ‘a finite, and in the context of the art, small or easily traversed, number of options ... would convince an ordinarily skilled artisan of obviousness.’”

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Purdue Pharma Prods. L.P. v. Par Pharm., Inc., 642 F. Supp. 2d 329, 368 (D. Del. 2009) (quoting *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008)); accord *C.W. Zumbiel Co., Inc. v. Kappos*, 702 F.3d 1371, 1387 (Fed. Cir. 2012) (finding obviousness where the invention “involve[d] no more than the exercise of common sense in selecting one out of a finite—indeed very small—number of options”). In such a case, an invention is considered “obvious to try.” *Hoffmann-La Roche Inc. v. Apotex Inc.*, 748 F.3d 1326, 1332 (Fed. Cir. 2014) (finding claimed dosage obvious to try). Further, “if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond [that person’s] skill.” *KSR*, 550 U.S. at 417. “When the prior art provides the means of making the invention and predicts the results, and the patentee merely verifies the expectation through ‘routine testing,’ the claims are obvious.” *Purdue Pharma*, 642 F. Supp. 2d at 368 (citing *Pfizer*, 480 F.3d at 1367).

“Obviousness does not require absolute predictability of success”; rather, “[a]ll that is required is a reasonable expectation of success” in making the invention via the combination. *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (citation omitted); *see also Duramed Pharms., Inc. v. Watson Labs., Inc.*, 413 Fed. App’x. 289, 294 (Fed. Cir. 2011) (“[T]here is no requirement that a teaching in the prior art be scientifically tested or even guarantee success before providing a reason to combine. Rather, it is sufficient that one of ordinary skill in the art would perceive from the prior art a reasonable likelihood of success.”) (citations omitted).

“In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the

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objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103.” *KSR*, 550 U.S. at 419. “[T]he path that leads an inventor to the invention is expressly made irrelevant to patentability by statute.” *Life Techs., Inc. v. Clontech Labs., Inc.*, 224 F.3d 1320, 1325 (Fed. Cir. 2000); *see also Standard Oil* 774 F.2d at 454 (“[O]ne should not go about determining obviousness under § 103 by inquiring into what patentees ... would have known or would likely have done.”) (emphasis omitted). The inquiry into whether prior art teachings would have rendered the claimed invention obvious to one of ordinary skill in the art, is, as a matter of law, “independent of the motivations that led the inventors to the claimed invention.” *Life Techs.*, 224 F.3d at 1325.

“One of the ways in which a patent’s subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent’s claim.” *KSR*, 550 U.S. at 419-20; *see also Norgren Inc. v. ITC*, 699 F.3d 1317, 1326-27 (Fed. Cir. 2012) (affirming invalidity of claims under § 103 where the claimed invention solved known problems by the use of an obvious solution). Even more, the discovery of a problem does not always result in a patentable invention. *Norgren*, 699 F.3d at 1327. For instance, an alleged invention is obvious in view of “evidence of known problems and an obvious solution.” *Id.*

“Where a variable is known to affect a particular desirable result, *i.e.*, is what has been called a ‘result-effective’ variable, the ‘overlap itself provides sufficient motivation to optimize the ranges,’ and ‘it is not inventive to discover the optimum or workable ranges by routine experimentation,’ because the desire to improve results would motivate skilled artisans to experiment with, and improve upon, known conditions in the prior art.” *In re Haase*, 542 Fed. App’x. 962, 967 (Fed. Cir. 2013) (citing *In re Applied Materials, Inc.*, 692 F.3d 1289, 1295-96

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(Fed. Cir. 2012)). “[R]anges that are not especially broad invite routine experimentation to discover optimum values, rather than require nonobvious invention....” *In re Peterson*, 315 F.3d 1325, 1330 n.1 (Fed. Cir. 2003). “[A] claim to a product does not become nonobvious simply because the patent specification provides a more comprehensive explication of the known relationships between the variables and the affected properties.” *In re Applied Materials, Inc.*, 692 F.3d at 1297.

4. Secondary Considerations

A court also considers in its obviousness analysis secondary considerations of nonobviousness that may bear on the issue of whether the claimed invention would have been obvious. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The purpose of secondary considerations of nonobviousness is to “check against hindsight bias.” *Bristol-Myers Squibb Co. v. Teva Pharm. USA, Inc.*, 752 F.3d 967, 977 (Fed. Cir. 2014); *accord Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1290 (Fed. Cir. 2006) (explaining that secondary considerations guard against hindsight). Objective evidence of nonobviousness “can include evidence of commercial success, long felt but unsolved needs, and failure of others, as well as unexpected results created by the claimed invention, unexpected properties of the claimed invention, licenses showing industry respect for the invention, and skepticism of skilled artisans before the invention.” *Aventis Pharma S.A. v. Hospira, Inc.*, 743 F. Supp. 2d 305, 344 (D. Del. 2010) (citation omitted); *see also Imperial Chemical Industries, PLC v. Danbury Pharmacal, Inc.*, 777 F. Supp. 330, 372 & n.91 (D. Del. 1991). Plaintiffs bear the burden of production with respect to evidence of any alleged objective indicia of nonobviousness. *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 719 F.3d 1346, 1354 (Fed. Cir. 2013) (discussing that the burden of production shifts to the patentee “once the court determine[s] that the challenger has established

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a prima facie case of obviousness”); *see also Prometheus Labs.*, 805 F.3d at 1101-02. Secondary considerations can also affirmatively support a finding of obviousness. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 18 (1966) (“As indicia of obviousness or nonobviousness, these inquiries may have relevancy.”).

Secondary considerations, moreover, cannot override a strong prima facie showing of obviousness. *See, e.g., Agrizap, Inc. v. Woodstream Corp.*, 520 F.3d 1337, 1344 (Fed. Cir. 2008); *Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1344 (Fed. Cir. 2013) (“[W]here a claimed invention represents no more than the predictable use of prior art elements according to established functions, ... evidence of secondary indicia are frequently deemed inadequate to establish non-obviousness.”); *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007) (“[G]iven the strength of the prima facie obviousness showing, the evidence on secondary considerations was inadequate to overcome a final conclusion that [the claim] would have been obvious.”); *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1371 (Fed. Cir. 2006) (“[S]econdary considerations of nonobviousness are insufficient as a matter of law to overcome our conclusion that... [the] claim [at issue] would have been obvious.”); *Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1484 (Fed. Cir. 1997); *Bristol-Myers Squibb Co. v. Teva Pharms. USA, Inc.*, 923 F. Supp. 2d 602, 686 (D. Del. 2013) (stating that despite finding the objective indicia of nonobviousness, “[t]he totality of that evidence did not strongly persuade the Court as to [the invention’s] nonobviousness”).

a) Nexus

“For objective evidence of secondary considerations to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the *claimed invention*. Where the offered secondary consideration actually results from something other than what is

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both claimed and *novel* in the claim, there is no nexus to the merits of the claimed invention.” *In re Huai-Hung Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011) (citations omitted); *see also GPAC*, 57 F.3d at 1580 (“For objective evidence to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention.”). Even “impressive” evidence of secondary considerations is not “entitled to weight” unless “it is relevant to the claims at issue.” *In re Paulsen*, 30 F.3d 1475, 1482 (Fed. Cir. 1994). Nexus requires a direct connection to the claimed features of the invention as recited in the language of the patent claims. *See, e.g., B.E. Meyers & Co. v. U.S.*, 47 Fed. Cl. 375, 378-79 (Fed. Cl. 2000).

Courts have routinely excluded evidence of secondary considerations absent a showing of nexus. *See, e.g., Cot’n Wash, Inc. v. Henkel Corp.*, 56 F. Supp. 3d 626, 651 (D. Del. 2014) (excluding expert testimony regarding industry praise where no nexus existed), *aff’d sub nom. Cot’n Wash Inc. v. Sun Prods. Corp.*, 606 F. App’x. 1009 (Fed. Cir. 2015); *Inventio AG v. Thyssenkrupp Elevator Corp.*, Civil Action No. 08-00874-RGA, 2014 WL 5786668, at *8 (D. Del. Nov. 6, 2014) (evidence of secondary considerations properly excluded where plaintiff failed to show nexus to claimed invention), *aff’d*, 622 F. App’x. 906 (Fed. Cir. 2015).

To fulfill the nexus requirement, the proffered evidence of secondary considerations must also be commensurate in scope with the asserted claims. *See Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1325, 1336 (Fed. Cir. 2010) (“Because the claims are broad enough to cover devices that either do or do not solve the ‘short fill’ problem, Abbott’s objective evidence of non-obviousness fails because it is not ‘commensurate in scope with the claims which the evidence is offered to support.’” (citation omitted)); *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1328 (Fed. Cir. 2008) (“[S]econdary considerations may presumptively be attributed to the patented invention only where ‘the marketed product embodies the claimed

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features, and is coextensive with them.” (citations omitted)); *MeadWestVaco Corp. v. Rexam Beauty & Closures, Inc.*, 731 F.3d 1258, 1264-65 (Fed. Cir. 2013) (holding that district court erred where its “analysis of the secondary considerations of nonobviousness involved only fragrance-specific uses, but the [asserted claims] are not fragrance-specific”); *Asyst Techs., Inc. v. Emtrak, Inc.*, 544 F.3d 1310, 1316 (Fed. Cir. 2008) (“[O]bjective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support.”) (quote omitted). Thus, if evidence of secondary considerations relates to a narrow aspect of a much broader claim, such evidence is not commensurate with the scope of the claims and fails to establish the non-obviousness of the asserted claims. See *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1325, 1336 (Fed. Cir. 2010). Likewise, merely “being the first commercially-available ... treatment” for a particular condition does not create the requisite nexus between the claims of the patent-in-suit and an alleged commercial embodiment thereof when the prior art disclosed that treatment. *Novartis AG v. Torrent Pharm. Ltd.*, 853 F.3d 1316, 1331 (Fed. Cir. 2017).

Nexus must be established through specific evidence. See *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996) (party asserting secondary considerations “must submit some factual evidence that demonstrates the nexus”); see also *In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984). No presumption of nexus exists unless the patentee can demonstrate that “the product embodies the claimed features, and is coextensive with them.” *WesternGeco LLC v. ION Geophysical Corp.*, 889 F.3d 1308, 1330 (Fed. Cir. 2018) (quotation omitted).

b) Commercial Success

When asserted as evidence of nonobviousness, “[c]ommercial success is relevant because the law presumes an idea would successfully have been brought to market sooner, in response to

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market forces, had the idea been obvious to persons skilled in the art.” *Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1376 (Fed. Cir. 2005). Thus, commercial success is tied “directly to the practical, financial source of impetus for research and development.” *Id.* at 1377 (quoting *In re Fielder*, 471 F.2d 640, 644 (C.C.P.A. 1973)).

As with other secondary considerations, “for commercial success to be probative evidence of nonobviousness, a nexus must be shown between the claimed invention and the evidence of commercial success.” *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356, 1363 (Fed. Cir. 2012).

Where other “factors [a]re identified as contributing to . . . commercial success, including marketing efforts,” “the fact that [a commercial embodiment of the claimed invention is] successful does not alter the obviousness analysis.” *Id.* (quotes omitted). If “the evidence does not show that the success of [the] product [i]s directly attributable to [the claimed invention],” the Court must “discount[] the evidence of commercial success as a secondary consideration rebutting [the] showing that the claimed invention would have been obvious.” *Id.* at 1364.

Moreover, “if the feature that creates the commercial success was known in the prior art, the success is not pertinent.” *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006); accord *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1369 (Fed. Cir. 2011) (“If commercial success is due to an element in the prior art, no nexus exists.”); *J.T. Eaton & Co. v. Atl. Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997) (“[T]he asserted commercial success of the product must be due to the merits of the claimed invention beyond what was readily available in the prior art.”).

Where a “product embodie[s] at least two patents,” the patentee is not entitled to a “presumption of nexus” because that is “not a situation where the success of a product can be

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attributed to a single patent.” *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1289, 1299 (Fed. Cir. 2010), *reh’g en banc granted, opinion vacated on other grounds*, 374 F. App’x 35 (Fed. Cir. 2010), and *opinion reinstated in part*, 649 F.3d 1276 (Fed. Cir. 2011).

c) Unexpected Results

Whether there are unexpected results is a question of fact. *In re Peterson*, 315 F.3d 1325, 1331 (Fed. Cir. 2003). The relevant time period for this inquiry is whether the results would have been unexpected by one of ordinary skill in the art at the time of the patentee’s application and based on knowledge available at that time. *In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997). To support a finding of unexpected results, a patentee must “show that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the art would have found surprising or unexpected” compared to the closest prior art. *Id.* at 1469; *Bristol-Myers Squibb Co.*, 752 F.3d at 977 (“To be particularly probative, evidence of unexpected results must establish that there is a difference between the results obtained and those of the closest prior art, and that the difference would not have been expected by one of ordinary skill in the art at the time of the invention.”); *Alcon, Inc. v. Teva Pharm. USA, Inc.*, 664 F. Supp. 2d 443, 464 (D. Del. 2009) (“When ‘unexpected’ and ‘significant’ differences exist between the properties of the claimed invention and those of the prior art, a finding of nonobviousness may be warranted.”). This showing requires “factual evidence,” not merely the unsupported assertions of counsel. *In re Youngblood*, 215 F.3d 1342, at *7 (Fed. Cir. July 6, 1999) (deeming unsupported assertions “insufficient”). And any evidence that is in fact provided should be “weighed against contrary evidence indicating that the results were not unexpected or not a substantial improvement over the prior art.” *See Santarus, Inc. v. Par Pharm., Inc.*, 720 F. Supp. 2d 427, 457 (D. Del. 2010), *rev’d on other grounds*, 694 F.3d 1344 (Fed. Cir. 2012).

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To assert that results were unexpected, “the patent owner must first show ‘what properties were expected.’” *Aventis Pharma S.A. v. Hospira, Inc.*, 743 F. Supp. 2d 305, 348 (D. Del. 2010) (citation omitted); *see also Pfizer*, 480 F.3d at 1371 (“[I]n order to properly evaluate whether a superior property was unexpected, the court should have considered what properties were expected.”). Any unexpected property must prove to be a significant benefit in comparison to the prior art. *See Bristol-Myers*, 752 F.3d at 977 (“Unexpected properties, however, do not necessarily guarantee that a new compound is nonobvious. While a ‘marked superiority’ in an expected property may be enough in some circumstances to render a compound patentable, a ‘mere difference in degree’ is insufficient.”); *Santarus*, 720 F. Supp. 2d at 457 (stating that “a party [claiming unexpected results] must produce evidence demonstrating substantially improved results that are unexpected in light of the prior art”) (citation omitted). Further, in order to assert unexpected results, a patentee must present evidence that the results claimed to be unexpected actually occurred. *In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984) (“It is well settled that unexpected results must be established by factual evidence.”). Speculation or unproven hypotheses about what might become an unexpected result are simply not enough. *See In re Geisler*, 116 F.3d at 1470 (finding unpersuasive a statement that it was “common sense” that an effect was unexpected).

Any evidence of an unexpected result must be commensurate with the scope of the claimed invention. *In re Grasseli*, 713 F.2d 731, 743 (Fed. Cir. 1983). The patentee must compare the results achieved by the claimed invention with the results achieved by the closest prior art to determine whether they are unexpected. *In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984). And any evidence that is in fact provided should be “weighed against contrary evidence indicating that the results were not unexpected or not a substantial improvement over

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the prior art.” *See Santarus*, 720 F. Supp. 2d at 457.

“Unexpected results that are probative of non-obviousness are those that are different in kind and not merely in degree from the results of the prior art.” *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 739 (Fed. Cir. 2013) (citations omitted); *see also Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1322-23 (Fed. Cir. 2004) (“[E]ven though [a] modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art, unless the claimed [invention] produce[s] a new and unexpected result which is different in kind and not merely in degree from the results of the prior art.”) (quotation omitted); *Bristol-Myers Squibb*, 752 F.3d at 977 (“a ‘mere difference in degree’ is insufficient”). Moreover, just as unexpected results may provide evidence of nonobviousness, “[e]xpected beneficial results” provide additional “evidence of obviousness.” *In re Gershon*, 372 F.2d 535, 537 (C.C.P.A. 1967).

As with other secondary considerations, even where a claimed invention “exhibits unexpectedly superior results,” “this secondary consideration does not overcome [a] strong showing of obviousness.” *Pfizer*, 480 F.3d at 1372. Where “the record establishes such... a strong case of obviousness,” any “alleged unexpectedly superior results are ultimately insufficient.” *Id.* In particular, “evidence of superior [results] does nothing to undercut the showing that there was a reasonable expectation of success . . . even if the level of success may have turned out to be somewhat greater than would have been expected.” *Hoffmann-La Roche Inc. v. Apotex Inc.*, 748 F.3d 1326, 1334 (Fed. Cir. 2014).

d) *Long-Felt But Unmet Need*

To demonstrate a long-felt but unmet need, the patentee must point to an “articulated identified problem and evidence of efforts to solve that problem” which were unsuccessful

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before the invention, which was alleviated by the patented invention. *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1332 (Fed. Cir. 2009) (quotation omitted). Thus, the patentee must submit “actual evidence of a long-felt need, as opposed to argument.” *In re Kahn*, 441 F.3d 977, 990 (Fed. Cir. 2006).

Long-felt but unmet need is analyzed as of the filing date of the patent at issue. *See Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1332 (Fed. Cir. 2009). In order to establish that a long-felt but unmet need existed, a patentee must provide evidence that there was a long-felt but unmet need for the claimed *invention*. *See In re Gardner*, 449 Fed. App’x. 914, 918 (Fed. Cir. 2011) (“[T]he Board determined that the argument was unsupported by any evidence, and failed to establish that a long-felt need existed for the claimed invention as opposed to extended range vehicles of unspecified configuration and operation.”).

“Where the differences between the prior art and the claimed invention are [] minimal ... it cannot be said that any long-felt need was unsolved.” *Geo. M. Martin*, 618 F.3d at 1304; *see also Ethicon Endo-Surgery, Inc. v. Covidien LP*, 812 F.3d 1023, 1035 (Fed. Cir. 2016). This is because even if a patented product improves “some aspects” of the available market, this is not evidence of an actual long-felt need existing. *May v. Carriage, Inc.*, 688 F. Supp. 408, 420 (N.D. Ind. 1988) (“Although the Stewart patent may have improved on some aspects of the slide-out room for travel trailers, there is no evidence of ‘long-felt need’ or failure of others in attempts to develop needed improvements.”).

Further, evidence of long-felt but unmet need is not probative if the prior art already solved the alleged need. *See Bristol-Myers Squibb*, 752 F.3d at 979 (noting that the evidence of long-felt but unmet need was of “limited value to BMS” because three other drugs were invented before and on the market before the drug at issue); *Aventis Pharma Deutschland GmbH v. Lupin*,

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Ltd., 2006 WL 2008962, at *45 (E.D. Va. July 17, 2006), *rev'd on other grounds*, 499 F.3d 1293 (Fed. Cir. 2007) (noting that where there are already “several effective” drugs of the same class on the market, courts have concluded that there is “simply [no] ... ‘long-felt need’ for another” one); *Geo. M. Martin*, 618 F.3d at 1304-05 (finding that evidence of long-felt but unmet need “d[id] not create a reasonable dispute as to obviousness” because the “‘need’ had been met by prior art machines”).

Once a long-felt need is established, a party must then put forth evidence showing that the claimed invention actually satisfied that need. *Gardner*, 449 Fed. App'x. at 918.

E. Obviousness-Type Double Patenting

Obviousness-type double patenting “prohibits claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent.” *Sun Pharms. Indus., Ltd. v. Eli Lilly and Co.*, 611 F.3d 1381, 1384-85 (Fed. Cir. 2010) (internal quotations omitted). This analysis involves a two-step process, where the court: (1) “construes the claims in the earlier patent and the claims in the later patent and determines the differences,” and then (2) “determines whether those differences render the claims patentably distinct.” *Id.* at 1385. If a later expiring claim is obvious over, or anticipated by, an earlier expiring claim, the later claim is not patentably distinct from the earlier claim. *Id.* Under those circumstances, the “later claim is invalid for obviousness-type double patenting.” *Id.*

F. Lack of Written Description

The determination that a patent is invalid for failure to meet the written description requirement is a question of fact. *PIN/NIP, Inc. v. Platte Chem. Co.*, 304 F.3d 1235, 1243 (Fed. Cir. 2002). A patent’s specification must “contain a written description of the invention.” 35 U.S.C. § 112(a). To comply with the written description requirement of § 112, a patentee must

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describe “the invention, with all its claimed limitations.” *ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1379 (Fed. Cir. 2009) (citation omitted). A specification provides adequate written description if it reasonably conveys to a person of ordinary skill in the art that “the inventor had possession of the claimed subject matter as of the filing date.” *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010).

Merely describing one embodiment of a claimed invention does not necessarily satisfy the written description requirement; rather, description of a “single embodiment would support... a generic claim only if the specification would reasonably convey to a person skilled in the art that [the inventor] had possession of the claimed subject matter at the time of filing.” *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1346 (Fed. Cir. 2005) (citation and internal quotation marks omitted). Further, “a patentee cannot always satisfy the requirements of section 112, in supporting expansive claim language, merely by clearly describing one embodiment of the thing claimed.” *Id.* The specification itself must demonstrate that the inventor was in possession of the entirety of the claimed invention. *Ariad Pharms.*, 598 F.3d at 1352. Therefore, the written description requirement is not necessarily met because the claim language appears in the patent specification. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 968-969 (Fed. Cir. 2002).

The Federal Circuit has articulated a variety of factors to evaluate the adequacy of the disclosure supporting generic claims, including (1) the existing knowledge in the particular field, the extent and content of the prior art, (3) the maturity of the science or technology, and (4) the predictability of the aspect at issue. *Ariad*, 598 F.3d at 1351 (citing *Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005)). “A ‘mere wish or plan’ for obtaining the claimed invention is not adequate written description.” *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341,

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1348 (Fed. Cir. 2011) (citation omitted). A claimed invention having an inoperable or impossible claim limitation lacks an enabling disclosure under 35 U.S.C. § 112. *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 956 (Fed. Cir. 1983). If the number of inoperative combinations becomes significant, and thereby forces one of ordinary skill in the art to experiment unduly to be able to practice the claimed invention, the claims are invalid. *Durel Corp. v. Osram Sylvania Inc.*, 256 F.3d 1298, 1306 (Fed. Cir. 2001) (citing *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1576-77 (Fed. Cir. 1984)); see also *Boston Sci. Corp. v. Johnson & Johnson Inc.*, 679 F. Supp. 2d 539, 556 (D. Del. 2010), *aff'd sub nom. Boston Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353 (Fed. Cir. 2011) (holding claims invalid where the claims, “as written, implicate[d] an indeterminable number of inoperative embodiments,” and would require undue experimentation). The level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology. *Ariad*, 598 F.3d at 1351.

G. Lack of Enablement

35 U.S.C. § 112 ¶ 1 requires that a patent applicant disclose their invention such that a person of ordinary skill in the art would be able to practice the full scope of the claimed invention without having to resort to undue experimentation. See *ALZA Corp. v. Andrx Pharm., LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010); see also *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (“[I]t is well established that enablement requires that the specification teach those in the art to make and use the invention without undue experimentation.”). Whether the enablement requirement is met is a question of law and is determined as of the filing date of the application. *ALZA*, 603 F.3d at 940; *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1070 (Fed. Cir. 2005). Lack of enablement must be proven by clear and convincing evidence. *Auto. Techs. Int’l, Inc. v. BMW of*

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N. Am., Inc., 501 F.3d 1274, 1281 (Fed. Cir. 2007). Enablement is determined from the perspective of a person of ordinary skill in the art. *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1371-72 (Fed. Cir. 1999).

“To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without ‘undue experimentation.’” *ALZA*, 603 F.3d at 940 (citation omitted); *see also In re Goodman*, 11 F.3d 1046, 1049 (Fed. Cir. 1993) (holding that “‘the specification must teach those of skill in the art how to make and how to use the invention as broadly as it is claimed’”) (quote omitted). Whether undue experimentation would have been required is a question of law based on underlying facts. *Enzo Biochem*, 188 F.3d at 1369. The person of ordinary skill in the art’s knowledge is not a “substitute for a basic enabling disclosure.” *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997) (recognizing that specification, not knowledge of person of ordinary skill in the art, must disclose the novel aspects of an invention to enable claims to that invention). “Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations.” *In re Wands*, 858 F.2d at 737.

In *In re Wands*, the Federal Circuit set forth a set of factors to guide the inquiry into whether experimentation is undue (the Wands factors): (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *In re Wands*, 858 F.2d at 737. Not all of the Wands factors have to be present to find undue experimentation was necessary to practice an invention. *See Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991) (noting that the Wands factors “are

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illustrative, not mandatory”).

35 U.S.C. § 112 sets forth that a patentee must describe how to make and use the claimed inventions. *See In re ‘318 Patent Infringement Litig.*, 583 F.3d 1317, 1323-24 (Fed. Cir. 2009). In cases involving unpredictable factors, to be enabling, the specification must sufficiently disclose how to make and use the claimed invention. *See Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1254 (Fed. Cir. 2004). Less disclosure of actual experimentation is necessary if the art is more predictable. *See, e.g., Scott v. Finney*, 34 F.3d 1058, 1061-62 (Fed. Cir. 1994); *see also Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1533 (Fed. Cir. 1987).

For the unpredictable arts, disclosure of a single species is usually not enough to enable a broad claim. *See In re Curtis*, 354 F.3d 1347, 1358 (Fed. Cir. 2004) (“[A] patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when, as is the case here, the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed.”); *Bilstad v. Wakalopulos*, 386 F.3d 1116, 1125 (Fed. Cir. 2004) (“[I]f the art is unpredictable, then disclosure of more species is necessary to adequately show possession of the entire genus.”); *Regents of the Univ. of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1569 (Fed. Cir. 1997) (noting that with regard to chemical claims, “[i]t has been consistently held that the naming of one member of such a group is not, in itself, a proper basis for a claim to the entire group”) (quoting *In re Grimme*, 274 F.2d 949, 952, 124 USPQ 499, 501 (Cust. & Pat.App. 1960)). The breadth of the claims dictates the degree of necessary disclosure. *See In re Wright*, 999 F.2d 1557, 1562 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 496 (Fed. Cir. 1991) (holding “it is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art. However, there must be sufficient disclosure, either through illustrative examples or terminology,

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to teach those of ordinary skill how to make and use the invention as broadly as it is claimed.” (internal citations omitted)). Claiming too broadly, as for instance to cover inoperable subject matter, renders a claim invalid. *Alcon Research, Ltd. v. Apotex Inc.*, 687 F.3d 1362, 1368 (Fed. Cir. 2012) (“[Y]ou can’t simply disavow the invalid portion and keep the valid portion of the claim.”).

H. Indefiniteness

A patent’s claims must “particularly point[] out and distinctly claim[] the subject matter which the inventor or a joint inventor regards as the invention.” 35 U.S.C. § 112(b). Whether a claim is invalid for indefiniteness is a question of law. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015).

“[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014). There are several aspects to the indefiniteness inquiry. *Id.* at 2128. First, “definiteness is to be evaluated from the perspective of someone skilled in the relevant art.” *Id.* Second, “in assessing definiteness, claims are to be read in light of the patent’s specification and prosecution history.” *Id.* Lastly, “[d]efiniteness is measured from the viewpoint of a person skilled in [the] art at the time the patent was filed.” *Id.* (emphasis omitted).

While “the definiteness requirement must take into account the inherent limitations of language,” “[a]t the same time, a patent must be precise enough to afford clear notice of what is claimed, thereby apprising the public of what is still open to them. Otherwise, there would be a zone of uncertainty which enterprise and experimentation may enter only at the risk of

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infringement claims.” *Id.* at 2129 (internal citations and quotation marks omitted).

EXHIBIT 6

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH LLC, WYETH)	
PHARMACEUTICALS LLC, PF PRISM)	
C.V., PBG PUERTO RICO LLC and)	
PF PRISM IMB B.V.)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 16-1305 (RGA)
)	CONSOLIDATED
SUN PHARMACEUTICAL INDUSTRIES)	
LIMITED and SUN PHARMACEUTICAL)	
INDUSTRIES, INC.,)	
)	
Defendants.)	
)	
)	

PLAINTIFFS' LIST OF WITNESSES

1. Plaintiffs Wyeth LLC, Wyeth Pharmaceuticals LLC, PF PRISM C.V., PBG Puerto Rico LLC, and PF PRISM IMB B.V. (“Pfizer” or “Plaintiffs”) expect to call some or all of the witnesses identified below either live or by deposition (transcript or video).

2. Plaintiffs reserve the right to call substitute witnesses to the extent that a witness’s circumstances change, or a witness becomes unavailable for trial. Plaintiffs further reserve the right to call any witness for impeachment purposes.

3. Plaintiffs reserve the right to call one or more witnesses not identified below whose testimony is necessary to establish the admissibility of a trial exhibit if the admissibility of the exhibit is challenged by Defendants.

4. Plaintiffs reserve the right to call any witness listed on Defendants’ Witness List or required to rebut Defendants’ case.

5. Plaintiffs reserve the right to call any additional witnesses necessitated by any of the Court’s pretrial or trial rulings, or additional witnesses to respond to issues raised after the submission of this list.

6. By identifying these witnesses, Plaintiffs are not required to call them at trial, nor are Plaintiffs limited in the manner in which such testimony is presented at trial.

I. PLAINTIFFS’ LIST OF EXPERT AND FACT WITNESSES

7. Plaintiffs identify the following witnesses:

Expert Witnesses	
Witness	Form of Testimony
Leonard J. Chyall, Ph.D.	Live
Mark J. Levis, M.D., Ph.D.	Live
Mark A. Mureko, Ph.D.	Live

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Expert Witnesses	
Witness	Form of Testimony
Neil. P. Shah, M.D., Ph.D.	Live
Bernhardt L. Trout, Ph.D.	Live

Fact Witnesses	
Witness	Form of Testimony
Kim T. Arndt, Ph.D.	Live (may call)
Frank Boschelli, Ph.D.	Live (will call)
David Clarke, Ph.D.	Live (will call)
Jennifer M. Golas	Live (may call)
Edward Gramling	Live (may call)
Diane H. Boschelli, Ph.D.	Deposition
Gregg Feigelson, Ph.D.	Deposition
Judy Lucas	Deposition
Bharati Nadkarni, Ph.D.	Deposition
Henry Strong	Deposition
Marc S. Tesconi, Ph.D.	Deposition
Hong Wen, Ph.D.	Deposition

II. OVERVIEW OF PLAINTIFFS' EXPERT WITNESSES

8. Dr. Leonard Chyall received a B.A. degree from Oberlin College with a major in chemistry in 1986 and a Ph.D. in chemistry from the University of Minnesota in 1991. Dr. Chyall was a postdoctoral fellow in the chemistry department at Purdue University from 1992-

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1996. Dr. Chyall has spent his career working in the fields of analytical and organic chemistry and has extensive experience with the characterization of pharmaceutical solids, including use of X-ray powder diffraction, X-ray crystallography, and other analytical techniques. Plaintiffs anticipate that Dr. Chyall will offer testimony concerning (i) background on characterization of pharmaceutical solids; (ii) infringement of the '678 patent by Sun; and (iii) validity of the '678 patent as not indefinite, not anticipated, not obvious, and not invalid for obviousness-type double patenting.

9. Dr. Mark Levis received an A.B. degree in genetics from the University of California, Berkeley in 1985, a Ph.D. in biochemistry from the University of California, San Francisco School of Medicine in 1992, and an M.D. from the University of California, San Francisco School of Medicine in 1994. Dr. Levis completed a residency in internal medicine at the Osler Medical Service at Johns Hopkins University from 1996-1997, and a fellowship in medical oncology at the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University from 1999-2002. Dr. Levis is a Professor of Oncology at Johns Hopkins University, and is an attending physician at Johns Hopkins Hospital. Dr. Levis regularly treats CML patients as part of his clinical practice. Dr. Levis is also the Director of the Adult Leukemia Service and Co-Director of the Division of Hematologic Malignancies at the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins. Plaintiffs anticipate that Dr. Levis will offer testimony concerning (i) background on treatment of CML, including use of BCR-ABL1 kinase inhibitors; (ii) validity of the '148 patent for satisfying the written description and enablement requirements of Section 112, and (iii) validity of the '625 patent for satisfying the written description, enablement, and definiteness requirements of Section 112.

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10. Dr. Mark Murcko received a B.S. with a major in chemistry and a minor in applied mathematics from Fairfield University and a Ph.D. in organic chemistry from Yale University. From 1987-1990, Dr. Murcko worked at Merck Sharpe & Dohme, where he helped discovery clinical candidates for the treatment of cardiovascular and ocular diseases. In 1990, Dr. Murcko joined Vertex Pharmaceuticals as a founding scientist, and from 2001-2011 was the Chief Technology Officer and Chair of the Scientific Advisory Board for the company. At Vertex, Dr. Murcko co-invented Incivek™ (telaprevir), an HCV protease inhibitor, as well as two HIV-protease inhibitors, Agenerase™ (amprenavir) and Lexiva™ (fosamprenavir). At Vertex, Dr. Murcko was heavily involved in kinase research, including work on p38 MAP kinase, JAK3 kinase, and Aurora kinase. Plaintiffs anticipate that Dr. Murcko will offer testimony concerning (i) background on the development of kinase inhibitors, including background on development of structure-activity-relationships; and (ii) the validity of the '148 patent and '625 patent as not obvious.

11. Dr. Neil Shah received a B.S. in genetics from the University of California, Berkeley in 1984, a Ph.D. in microbiology and molecular genetics from the University of California, Los Angeles (UCLA) in 1992, and an M.D. from the UCLA School of Medicine in 1996. Dr. Shah completed an internship (1996-1997) and residency (1997-98) in internal medicine at UCLA, and a fellowship in hematology and oncology (1998-2003) at UCLA. From 2000-2006, Dr. Shah conducted research in the laboratory of Dr. Charles Sawyers, who was conducting the first-in-human study of imatinib, the first tyrosine kinase inhibitor to be evaluated for treatment of chronic myelogenous leukemia (CML). During this time, Dr. Shah also helped manage CML patients in the imatinib clinical trial. In 2006, Dr. Shah joined the faculty of University of California, San Francisco School of Medicine (UCSF). In 2012, Dr. Shah was

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named the Edward S. Ageno Distinguished Professor in Hematology/Oncology, and since 2017 has been a Professor in Residence at UCSF. Since 2006, Dr. Shah has also been a member of the faculty for the Biomedical Sciences Program and the Pharmaceutical Sciences & Pharmacogenomics Program at UCSF. In 2013, Dr. Shah became Leader of the Hematopoietic Malignancies Program in the Helen Diller Family Comprehensive Cancer Center at UCSF, and in 2015, became Director of the UCSF Molecular Medicine Residency Program. Dr. Shah's clinical activities have been focused on clinical trials for dasatinib for the treatment of imatinib-resistant and refractory CML and of other clinical studies with tyrosine kinase inhibitors of BCR-ABL1, JAK2, and FLT3. Dr. Shah currently treats over 150 patients with CML, and sees patients with other myeloproliferative disorders. Plaintiffs anticipate that Dr. Shah will offer testimony concerning (i) background on the biology of CML; (ii) background on the pre-clinical and clinical development of BCR-ABL1 kinase inhibitors for treatment of CML; (iii) how physicians prescribe and patients use BCR-ABL1 kinase inhibitors for treatment of CML; (iv) infringement of the '148 patent by Alembic and Sun; (v) infringement of the '625 patent by Sun; and (vi) the validity of the '148 patent and '625 patent as not obvious.

12. Dr. Bernhardt Trout received a B.S. and M.S. in chemical engineering from the Massachusetts Institute of Technology (MIT) in 1990, and a Ph.D. from the University of California, Berkeley in 1996. Dr. Trout conducted post-doctoral research at the Max-Planck Institute before joining MIT in 1998 as an Assistant Professor of Chemical Engineering. Dr. Trout is currently the Raymond F. Baddour, ScD, (1949) Professor of Chemical Engineering at MIT. Since 1998, Dr. Trout has conducted research in pharmaceutical formulation, and since 2002, Dr. Trout has conducted research on chemical pharmaceuticals, specifically crystallization of model compounds, including taking into account solid-dosage formulation issues. From

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2007-2019, Dr. Trout was the founding Director for the Novartis-MIT Center for Continuous Manufacturing, a partnership with the objective of transforming pharmaceutical manufacturing. Dr. Trout conducts research and assists pharmaceutical companies with research related to, among other things, pharmaceutical development, manufacturing, formulation, and stability. Dr. Trout also has extensive experience in the regulatory aspects of pharmaceuticals as a consultant with the U.S. Food and Drug Administration (FDA) and engagements with the European Medicines Agency (EMA) and the Pharmaceutical and Medical Devices Agency (PMDA) of Japan. Plaintiffs anticipate that Dr. Trout will offer testimony concerning (i) background on the considerations in making a pharmaceutically acceptable composition; and (ii) the validity of the '625 patent as not anticipated.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH LLC, WYETH PHARMACEUTICALS)	
LLC, PF PRISM C.V., PBG PUERTO RICO LLC,)	
and PF PRISM IMB B.V.,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 16-1305 (RGA)
)	
SUN PHARMACEUTICAL INDUSTRIES)	(Consolidated)
LIMITED, and SUN PHARMACEUTICAL)	
INDUSTRIES, INC.,)	
Defendants.)	
)	
)	

DEFENDANTS' WITNESS LIST

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1. Defendants Sun Pharmaceutical Industries Limited, and Sun Pharmaceutical Industries, Inc. (collectively “Sun” or “Defendants”) expect to call some or all of the witnesses identified below either live or by deposition (transcript or video).

2. Sun reserves the right to call substitute witnesses to the extent that a witness’s circumstances change, or a witness becomes unavailable for trial. Sun further reserves the right to call any witness for impeachment purposes.

3. Sun reserves the right to call one or more witnesses not identified below whose testimony is necessary to establish the admissibility of a trial exhibit if the admissibility of the exhibit is challenged by Plaintiffs.

4. Sun reserves the right to call any witness listed on Plaintiffs’ Witness List (Exhibit 6 of this proposed pretrial order) or required to rebut Plaintiffs’ case.

5. Sun reserves the right to call any additional witnesses necessitated by any of the Court’s pretrial or trial rulings, or additional witnesses to respond to issues raised after the submission of this list.

6. By identifying these witnesses, Sun is not required to call them at trial, nor is Sun limited in the manner in which such testimony is presented at trial.

I. SUN’S LIST OF EXPERT AND FACT WITNESSES

7. Sun identifies the following witnesses:

Expert Witnesses	
Witness	Form of Testimony
Piotr Karpinski, Ph.D.	Live
Craig Lindsley, Ph.D.	Live
Michael Thirman, Ph.D.	Live

EXHIBIT 7

Fact Witnesses	
Witness	Form of Testimony
Kim T. Arndt, Ph.D.	Live (may call) or by Deposition
Frank Boschelli, Ph.D.	Live (may call) or by Deposition
David Clarke, Ph.D.	Live (may call) or by Deposition
Jennifer M. Golas	Live (may call) or by Deposition
Diane H. Boschelli, Ph.D.	Deposition
Gregg Feigelson, Ph.D.	Deposition
Judy Lucas	Deposition
Henry Strong	Deposition
Marc S. Tesconi, Ph.D.	Deposition
Hong Wen, Ph.D.	Deposition
Nicholas Donato	Deposition
Brian Druker	Deposition
James Gibbons	Deposition

II. OVERVIEW OF PLAINTIFFS' EXPERT WITNESSES**Piotr Karpinski, Ph.D.**

8. Dr. Piotr Karpinski received a Master of Science degree in chemistry with a minor in chemical engineering from Łódź University of Technology in Łódź, Poland in 1969 and a Ph.D. in chemistry from Wrocław University of Science and Technology In 1975. Dr. Karpinski received a Doctor of Science degree in chemical engineering from Wrocław University of Science and Technology in 1981. From 1971 to 1986, Dr. Karpinski was a professor of chemical

EXHIBIT 7

engineering for various educational institutions, including Wroclaw University of Science and Technology, Waseda University, Iowa State University, and Worcester Polytechnic Institute. In 1986, Dr. Karpinsky joined Eastman Kodak in Rochester, NY, first as a Senior Research Scientist, and later as a member of the Senior Research Staff. From 2000-2014, Dr. Karpinski was a Fellow and head of Novartis' Crystal Engineering Lab, Principal Fellow and head of Novartis' Physical Chemistry Lab, and Principal Fellow and leader of Novartis' Salt & Polymorphism and Particle Engineering Networks.

9. During his time at Novartis, Dr. Karpinski supervised all U.S. salt screening activities, salt programs, polymorphism programs, drug substance property evaluation, initial crystallization development studies, single crystal structures, as well as all U.S.-based releases for APIs, using analytical methods such as X-ray powder diffraction ("XRPD"), Fourier transform infrared spectroscopy ("FT-IR"), differential scanning calorimetry ("DSC"), thermogravimetric analysis ("TGA"), Raman spectroscopy, dynamic vapor sorption ("DVS"), and particle size distribution ("PSD").

10. Sun anticipates Dr. Karpinski will offer testimony concerning (i) background on analytical methods, including XRPD, DSC, and TGA; (ii) non-infringement of the '678 patent by Sun; and (iii) invalidity of the claims of the '678 patent as indefinite, anticipated, obvious, and under the doctrine of obviousness-type double patenting.

Craig Lindsley, Ph.D.

11. Dr. Craig Lindsley received a B.S. degree in Chemistry in 1992 from California State University, Chico, in Chico, CA, and a Ph.D. in Chemistry in 1996 from university of California, Santa Barbara, in Santa Barbara, CA. Dr. Lindsley was postdoctoral fellow at Harvard University from 1997 to 1999. Dr. Lindsley is a Professor of Pharmacology and

EXHIBIT 7

Professor of Chemistry at Vanderbilt University School of Medicine and School of the Arts and Sciences. Prior to joining Vanderbilt, Dr. Lindsley worked extensively in the pharmaceutical industry, as a Senior Scientist at Parke-Davis, a Senior Organic Chemist at Eli Lilly, and as a Senior Research Chemist and Senior Research Fellow at Merck Research Laboratories. Dr. Lindsley has extensive experience in drug discovery and development, particularly in the field of oncology and with various kinase inhibitors, including both serine-threonine kinase inhibitors and tyrosine kinase inhibitors, transporters, ion channels and GPCRs. While at Merck, Dr. Lindsley worked on numerous kinase programs, becoming extremely familiar with chronic myelogenous leukemia (“CML”), including development of the first allosteric Akt kinase inhibitors that enabled isoform specificity between Akt1, Akt2, and Akt3, and delivered key tool compounds as well as the Akt inhibitor MK-2206.

12. Sun anticipates Dr. Lindsley will offer testimony concerning (i) background on CML and the development of kinase inhibitors for the treatment of CML (ii) non-infringement of the '625 patent by Sun; (iii) lack of diligence in reducing the alleged invention to practice (iii) invalidity of claim 1 of the '625 patent as indefinite, not enabled, lacking sufficient written description, anticipated, and obvious; and (iv) invalidity of claims of the '148 patent as not enabled, lacking sufficient written description, and obvious.

Michael Thirman, Ph.D.

13. Dr. Michael Thirman earned a B.A. from the University of Michigan in 1982, and a Doctor of Medicine from the University of Michigan Medical School in 1996. Dr. Thirman was an Internal medicine Resident at the University of Minnesota Hospitals from 1986-1989, and served as a clinical fellow in the University of Chicago Section of hematology and Oncology from 1990-1994. Dr. Thirman is currently the Director of Leukemia Biology and an Associate

EXHIBIT 7

Professor in the Section of Hematology and Oncology at the University of Chicago. Dr. Thirman previously served as the Co-Program Director at the University of Chicago Cancer Research Center, focusing on Hematopoiesis and Hematologic Malignancies. Dr. Thirman has extensive knowledge and experience in the research and treatment of various types of blood cancers including chronic myelogenous leukemia (CML).

14. Sun anticipates Dr. Thirman will offer testimony that claims of the '148 patent and '625 patent did not satisfy a long-felt but unmet need.

EXHIBIT 8

EXHIBIT 8

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH LLC, WYETH PHARMACEUTICALS)	
LLC, PF PRISM C.V., PBG PUERTO RICO LLC,)	
and PF PRISM IMB B.V.,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 16-1305 (RGA)
)	
SUN PHARMACEUTICAL INDUSTRIES)	(Consolidated)
LIMITED, and SUN PHARMACEUTICAL)	
INDUSTRIES, INC.,)	
Defendants.)	
)	
)	

PLAINTIFFS' DEPOSITION DESIGNATIONS

EXHIBIT 8**ABBREVIATION AND FEDERAL RULE OF EVIDENCE
KEY TO THE OBJECTIONS**

ABBREVIATION	OBJECTION	APPLICABLE RULE(S)
A	Requires authentication or identification	FRE 901
B	Best evidence rules prohibit introduction	FRE 1001-1002
C	Improper compilation of separate documents	FRE 403, 901
D	Improper designation (designation is neither a question or testimony)	FRE 401, 402
E	Improper examination (vague, ambiguous, loaded, leading, etc.)	FRE 402, 403, 602, 611
F	Lack of foundation/personal knowledge (including calls for speculation)	FRE 402, 403, 602, 611
H	Hearsay if offered for the truth of the matter asserted	FRE 801, 802
I	Incomplete document or testimony	FRE 106, 403
M	Offer or discussion for settlement or compromise	FRE 408
N	Exhibit not produced in discovery	FRE 403
O	Improper opinion testimony	FRE 701-704
P	Privileged or attorney work product	FRE 501, 502
R	Lack of relevance	FRE 401, 402
S	Summary requiring underlying data or information	FRE 1006
T	Beyond the scope of the Rule 30(b)(6) topic for which a witness has been designated	FRE 602, FRCP 30(b)(6)
U	Unduly prejudicial, wasteful, confusing, misleading or cumulative	FRE 403

EXHIBIT 8

Deposition of Bharati Nadkarni December 4, 2018			
Plaintiffs' Designation	Defendants' Objections	Defendants' Counter-Designation	Plaintiffs' Objection to Counter-Designation
10:9-11			
11:12-12:5	U		
12:8-22	U		
13:9-19	I	13:20-14:21	
15:21-16:5			
16:11-15			
17:7-21	I	16:25-17:6; 17:22-18:4; 18:8-18:10; 18:12-18:25	
28:24-29:14	U		
29:21-30:2	U		
30:5-24	U		
31:3-14	U		
31:18-32:7, 9	U		
32:11-33:1	U		
33:4-16	U		
35:5-36:1	U		
36:4-11			
36:12-14, 16-19			
36:21-37:4	I	37:5-8	
37:9-11, 13-14	I	37:5-8	
37:24-38:1, 3			
38:4-15	I	38:16-17	
38:18-39:8			
45:18-46:19	I	46:20-24	
46:25-47:23			
49:8-51:13	U	51:14-18	
52:3-16	R, U	53:2-6; 56:17-57:9	
57:10-58:14		58:15-25	
59:1-9	R, U		
59:23-60:4	E		
61:7-62:3		62:4-6	
62:7-12		62:13-15; 62:17-21	
62:23-63:1			
66:6-23		66:24-67:5	
72:15-17	D, I		
72:21-25	F	73:1-73:13	
73:14-74:2	E, U, R	74:3-74:6	
74:7-75:5	R, U		
75:8-18	E, R, U		

EXHIBIT 8

Deposition of Bharati Nadkarni December 4, 2018			
Plaintiffs' Designation	Defendants' Objections	Defendants' Counter-Designation	Plaintiffs' Objection to Counter-Designation
84:14-85:5	U, R	85:6-16	
85:24-87:5	E, U		
88:10-16	R, U	88:17-23	
94:11-21	F, R, U	92:1-7	
98:8-20	R, U	98:21-24	
98:25-100:19	R, U	100:20-101:3	
101:4-16	F, E, R, U	101:17-102:9	
102:22-25	D, F, I		
103:7-10	F, I	103:11-13	
103:14-105:1	F, E		
109:3-111:12	E	111:24-112:6	
112:7-113:5	R, U	113:6-19	
114:12-15, 17-18	F, E, I	113:25-114:11	
116:15-23	F, I	116:25-117:1	
117:2-22	I, E		
119:7-11	F		
119:14-120:9	R, U		
122:1-13	I, F		
123:5-124:11	E, I, U	124:12-16	
124:17-22	E, U		
132:13-24	F	132:25-133:7	
133:8-15	F, E, U		
133:18-134:10	F, E, U	134:11-15	
134:16-135:2	U		
135:3-5, 7	R, U		
135:9-18	E, R, U		
135:23-136:13	E, U		
150:6-14	R, U, I	150:15-16	
150:17-151:6	R, U, I	151:7-17	
151:18-153:3	R, T, U, I	159:18-160:2; 160:4-5; 160:7-10; 160:12-17	
154:11-13	D, R, T, U, I		
154:15-155:15	R, T, U, I		
155:16-18, 21-156:16	R, T, U, I		
156:18-23, 157:2-4	R, T, U, I		
157:6-7, 11-13	R, T, U, I		
158:17-19, 23-159:3	R, T, U, I		
159:5-17	R, T, U, I		
161:9-11	R, U, I		
161:13-16	R, U, I		
161:23-162:21	R, U, I	162:22-163:5 164:8-9; 164:11-12	

EXHIBIT 8

Deposition of Bharati Nadkarni December 4, 2018			
Plaintiffs' Designation	Defendants' Objections	Defendants' Counter- Designation	Plaintiffs' Objection to Counter- Designation
163:6-9	R, U, I		
163:15-21	R, U, I		
164:4-7	R, U, I		
164:14-17	R, U, I		
164:18-19, 21	R, U, I		
164:23-24, 165:1-6	R, U, I		

EXHIBIT 8

Deposition of Diane H. Boschelli, Ph.D. November 30, 2018			
Plaintiffs' Designation	Defendants' Objections	Defendants' Counter-Designation	Plaintiffs' Objection to Counter-Designation
5:11-13			
9:4-19	U, R		
9:24-10:2	U, R		
10:4-7	U, R		
10:9-11	U, R		
10:15-22	U, R		
11:8-10	U, R		
11:13-19	U, R		
11:21-23	U, R		
11:25-12:2	U, R		
15:2-6	D, I	14:16-25	
15:12-16	F, I	15:17-19; 15:21-25; 16:2-3	
16:4-8	I	16:9-11; 16:13-15	
19:22-20:25	F		
21:2-22:16	F, D, I	22:17-25; 23:2-4	
51:5-15	F, D	49:8-25; 51:16-21; 51:23-52:11; 52:13-23.	
57:19-58:2	F, D	58:3-8	
59:18-19	I	59:23-25; 60:3-11; 60:14-24	
59:22	I		
68:22-69:10	I	69:24-70:5; 70:23-71:8; 71:10-72:3.	
69:12-14	I		
72:4-6	I		
72:8-15	I		
72:17-73:8	I		
73:9-10	I		
73:12-16	I		
73:17-18, 22-74:3	I		
79:14-80:17	E, I	83:4-9; 84:2-4; 84:6	
80:18-82:16	E, I		

EXHIBIT 8

Deposition of Gregg Feigelson, Ph.D. December 12, 2018			
Plaintiffs' Designation	Defendants' Objections	Defendants' Counter-Designation	Plaintiffs' Objection to Counter-Designation
8:25-9:1			
21:22-22:2	R, U		
22:7-10	R, U		
22:21-25	R, U		
23:7-15	R, U	23:16-22	
23:23-25	R, U		
24:1-14	R, U		
27:5-14	I	26:22-27: 4; 27:15-24	
28:9-11	I	27:25-28:8; 28:12-23	
30:14-16			
31:9-15	R, U		
32:18-20	F	31:24-32:17; 33:3-22	
37:3-17	F		
38:9-14	F	39:7-14	
40:3-4	F	40:7-13; 40:18-23	
40:7-9	F		
41:2-4	F		
54:5-10	F	54:11-14; 54:17-20	
54:22-55:24		55:11-14 55:22-23; 56:1-16	
55:3-4	I		
55:7	I		
55:9-10			
55:15-21			
58:4-5	I, U	58:18-20; 58:23-59:9; 59:12-23; 60:1-4	
58:8-10	I, U		
61:22-24	I, U	60:6-9; 60:12-18; 60:21- 61:5; 61:8-15; 61:18-20	
62:2-5	I, U		
62:7-9	I, U		
62:12-18	I, U		
65:11-14	I, U	64:16-17; 64:20-65:4; 65:7-9; 66:9-10; 66:13- 22	
65:17-66:8	I, U		
66:23-67:11	F	67:12-68:3; 68:6-69:25	
70:1-9	F		
77:11-16	F		
77:17-19	F, I		

EXHIBIT 8

Deposition of Gregg Feigelson, Ph.D. December 12, 2018			
Plaintiffs' Designation	Defendants' Objections	Defendants' Counter-Designation	Plaintiffs' Objection to Counter-Designation
77:22-78:5	I	78:22-79:1	
78:8-11	I		
79:4-8	I		
79:20-23	I	80:1-4	
80:5-16			
82:6-13	I	81:12-15; 81:18-82:5; 83:4-8; 83:11-12	
82:16-83:2	I		
85:8-11	I	85:12	
85:16-25	U		
86:1-4	I		
86:7-16	I	86:18-20; 86:23-87:2	
89:10-13	F	88:21-89:9; 89:14-90:7	
91:20-92:11	F	92:12-14; 92:17-93:1; 93:4-7	
94:7-9	I	97:10-13; 94:18-22; 95:9-15; 95:18-24; 96:14-16; 96:20-22	
94:14-17	F		
96:2-4	I		
96:7-13	I		
96:24-25	I	97:1; 97:6-9; 98:20; 99:3-5; 99:8-10; 99:24-100:3; 100:6-7	
98:15-17	I		
98:21	I		
98:23-99:2	I		
99:11-13	I		
99:16-17	I		
99:19-23	I		
111:6-17		113:23-114:3	
115:15-17	I	115:24-116:5	
115:20-21	I		
116:6-8	I		
116:9	I		
116:12-14	I		
116:16-24	I		
117:2-3	I		
117:5-7	I		
117:10-11	I		
117:24-118:3	I, U	118:4-5	
155:24-156:5		157:22-24; 158:2-4; 160:18-161:5; 161:17; 162:5-6; 162:9-12	
156:12-16			
158:16-20	F		

EXHIBIT 8

Deposition of Gregg Feigelson, Ph.D. December 12, 2018			
Plaintiffs' Designation	Defendants' Objections	Defendants' Counter-Designation	Plaintiffs' Objection to Counter-Designation
161:18-24	F, I		
162:2-3	I		
163:1-6	I	163:21-164:8; 164:18-20; 164:24-165:12; 165:15-166:1; 166:19-167:14; 168:6-10; 168:14-169:2; 169:5-13; 170:13-17.	
163:8-13	I		
171:7-16		173:25-174: 7; 174:10-18; 174:21-175:3; 175:6-176:1; 176:4-9; 176:12-13.	
173:9-11			
176:15-177:7		177:8-12; 177:15-17	
177:19-23			
178:1-21			
181:23-182:7	I	182:10	
182:12-17	I		
182:20-22	I	182:24-183:6; 183:15-184:6; 184:8-9; 184:12-24; 185:2-3	
185:5-14	I		
185:7-18	U, I, D		
185:20-22			
186:1-19			
209:13-14	D, I, F	209:23-210:3	
210:4-8	F	210:9-15	
211:20-23		211:24-212:2	
212:3-213:4		213:5-11	
214:18-20	I	213:12-13; 213:16-18	
214:23-25	I		
216:10-13			
216:21-25			
217:1-11	I, U	217:12-15; 217:18-22; 217:25-218:1; 218:3-10; 218:13-219:4	
219:19-220:14	I, U		

EXHIBIT 8

Deposition of Gregg Feigelson, Ph.D. December 12, 2018			
Plaintiffs' Designation	Defendants' Objections	Defendants' Counter-Designation	Plaintiffs' Objection to Counter-Designation
221:13-18	D, I	221:19-222:14	
222:15-223:6	F, U	223:7-224:1; 224:12-22; 225:6-8; 225:10-11.	
226:10-18	F, I, U	226:19-21	
226:22-25	I, U	227:1-10; 227:13-25;	
228:6-13	U	228:3-4.	
228:16-17	I	229:12-14; 229:17-20	
228:20-229:11	I		
230:12-20	D, I, U	230:21-231:13	
231:14-232:8	I, U	232:11; 232:14-16	
232:22-25	I, U	232:11-12; 232:14-16	
		233:13-17	
232:12	I, U		
232:17-19	F, I, U		
233:3-11	I, U		
234:8-16	D, F, I	234:17-22	
234:23-235:16	U	237:6-8; 237:11-12	
236:23-237:5	U		
238:5-13	D, F, I, U	238:14-16	
238:17-239:5	I, U	239:10-13	
239:8	I, U	239:21-23; 240:1-7	
239:17-20	U		
240:23-241:5	D, F, I	241:6-8	
241:9-10	I, U	242:6-12; 242:15-21	
241:11-19	F, I, U	243:18-22	
241:24-242:5	U, I		
242:22-243:4	U, I		
243:7-17	U, I		
245:8-16	D, F, I, U	245:17-19	
245:20-246:8	F, I, U	246:9-12; 246:15-16	
246:18-23	F, I, U	246:24-247:1; 247:4-12	
248:4-11	D, F, I, U	248:12-18	
248:19-249:7		249:8-11	
249:15-22	I		
249:22-250:2		250:3-4; 250:7-12	
251:2-9	D, F, I, U	251:10-252:6; 252:9-10	
252:21-253:8		253:8-12; 253:15-16	
254:8-16	D, F, I, U	254:17-19	
254:20-255:15		255:16-18;	

EXHIBIT 8

Deposition of Gregg Feigelson, Ph.D. December 12, 2018			
Plaintiffs' Designation	Defendants' Objections	Defendants' Counter- Designation	Plaintiffs' Objection to Counter- Designation
		255:21-256:4	
256:20-25	D, F, I, U	257:1-3	
257:4-13		257:14-23	
263:10-22	F, U, I	262:11-263:9	
263:21-22	I		
263:25-264:1	I		
266:21-24		266:25-267:13	
267:24-268:12		268:13-15; 268:18-21	
270:7-13			
272:4-10			
272:11-20		272:21-273:5	
274:1-20		273:23-25	
276:9-19			
276:23-278:22			
278:24-284:20			

EXHIBIT 8

Deposition of Henry Strong January 11, 2019			
Plaintiffs' Designation	Defendants' Objections	Defendants' Counter- Designation	Plaintiffs' Objection to Counter- Designation
5:9-10			
8:15-19	R, U		
12:4-12	R, U		
12:16-18	R, U		
15:3-10	R, U		
15:13-22	R, U		
20:10-24	F		
21:25-22:8	F	22:9-20	
24:4-6	D, I,		
24:22-23	F	24:15-18	
25:22-26:3	U		
32:15-33:8	U	33:9-10; 33:12-34:12	
34:13-25	U		
39:24-40:25	D, F, U	35:6-25; 36:7-15; 39:19-23; 41:1-8; 41:10-20	
52:6-8	D, F, I	60:25-61:4; 61:12-18; 62:12-63:2 63:14-16; 63:18-19; 64:25-65:1; 65:3-5 66:1-12; 67:2-21	
52:25-53:1	I, U		
53:25-54:3	U		
63:3-13	U		
64:22-24	I		
65:7-13	I		
70:24-25	D, I	72:1-6 72:23-73:7	
71:11-25	U		
72:7-22	U		

EXHIBIT 8

Deposition of Hong Wen, Ph.D. January 3, 2019			
Plaintiffs' Designation	Defendants' Objections	Defendants' Counter- Designation	Plaintiffs' Objection to Counter- Designation
8:9-11	I	8:8	
18:11-19	R, U		
21:7-18	R	21:23-22:9	
26:23-27:2	I, U	27:3-8; 28:5-17	
27:15-17	F		
28:18-29:15	R, U	29:16-17	
36:1-6	F, U	35:19-25	
52:7-10	I		
52:12-23	I, U		
52:25-53:7	I		
53:9-19	I	53:20-24	
173:15-18	I, H, O, U		
173:20	I, H, O, U		
173:23-24	I, H, O, U		
174:1	I, H, O, U		
174:14-175:9	E, H		

EXHIBIT 8

Deposition of Judy Lucas January 8, 2019			
Plaintiffs' Designation	Defendants' Objections	Defendants' Counter- Designation	Plaintiffs' Objection to Counter- Designation
6:8-10			
10:23-11:9	F, I, U	9:14-10:5; 13:4-19; 15:25-16:7; 17:22- 18:14; 18:22-19:14	
11:12-22	F, I, U		
20:12-15	I, U		
36:18-37:10	F, I	36:9-17	
40:12-40:19	F, I	40:2-11; 40:20-21	
42:6-11	F, I		
42:15-45:6	F, I		
143:8-9	D, I		
143:15-17	I	143:18-21	
144:3-6	U	144:7-11; 144:14-18	
144:19-21	I		
144:24-145:4	I	146:2-3; 146:6-11; 146:15	
146:16-17	D, I	147:12-18; 148:12-14	
146:24-147:11	D, I		
147:19-148:11	I		
148:15-16	D, I		
148:21-25	I, U	149:5-151:2; 151:5- 20; 151:23-152:25; 153:4-11; 153:14- 155:4; 158:20-159:6; 161:15-21; 161:24	

EXHIBIT 8

Deposition of Marc S. Tesconi, Ph.D. January 8, 2019			
Plaintiffs' Designation	Defendants' Objections	Defendants' Counter-Designation	Plaintiffs' Objection to Counter-Designation
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43:11-16	R, U		
45:3-13	R, U		
45:16-46:9	R, U		
50:13-15	R, U		
50:18-25	R, U		
80:7-8	F, I		
80:10-11	F, I	80:13-18; 81:5-11	
109:22-25	D, I	110:1-4	
111:6-8	R, I, U		
111:10	R, I, U		
111:12-112:11	R, I, U		
112:12-21	R, I, U		
118:3-7	F, R, U	117:21-118:2	
118:9-16	R, U	118:17-22; 119:9-17	
120:5-11	F	120:12-14	
126:12-16	I, U	127:15-128:3	
128:7-13	R, U		
128:20-129:12	U, H	128:14-19	
130:2-14	F, H, U		
212:10-23	D, F, U		
214:6-20	D, I	214:22; 214:24-215:3	
216:2-6	D, I	216:7-24	
218:6-11			
218:17-25	I	219:4-11	
220:2-6	I	219:24-220:1	
225:13-227:3	U		
270:5-6	D, I		
270:14-18	I	270:19-25; 271:20-272:6	
274:14-17	I, U	274:18-21	
274:22-25			
275:8-276:24		276:25-277:11	
277:12-16	I		
277:18-24		278:1-6; 278:9-15	
315:9-13	D, F, I	315:14-24	
315:25-316:3	F, I	316:4-10	
316:16-317:2			

EXHIBIT 8

Deposition of Marc S. Tesconi, Ph.D. January 8, 2019			
Plaintiffs' Designation	Defendants' Objections	Defendants' Counter-Designation	Plaintiffs' Objection to Counter-Designation
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321:21-23	D, I	321:24-25	
322:1-4	F, I		
322:5-8	D, I	322:9-10	
322:11-15	F, U	322:16-24	
322:25-323:2	F, H		
323:8-9	I		
323:11-12	I		
327:19-22	D, F, I	327:23-328:5; 328:25-330:1	
328:6-8	F, I, U		
330:9-331:8		331:9-16	
336:9-336:23	I, U		
337:5-8	I, U		
337:14-16	I, U		
337:18-21	I, U, H		
343:22-344:10	I, U	344:11-345:13; 345:18-21	
345:23-346:10			
359:25	D, I, F, H		
360:1-2	D, I, F, H		
360:9-361:25	E, H, U		

EXHIBIT 9

EXHIBIT 9

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH LLC, WYETH PHARMACEUTICALS)	
LLC, PF PRISM C.V., PBG PUERTO RICO LLC,)	
and PF PRISM IMB B.V.,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 16-1305 (RGA)
)	
SUN PHARMACEUTICAL INDUSTRIES)	(Consolidated)
LIMITED, and SUN PHARMACEUTICAL)	
INDUSTRIES, INC.,)	
Defendants.)	
)	
)	

DEFENDANTS' DEPOSITION DESIGNATIONS

EXHIBIT 9**ABBREVIATION AND FEDERAL RULE OF EVIDENCE
KEY TO THE OBJECTIONS**

ABBREVIATION	OBJECTION	APPLICABLE RULE(S)
A	Requires authentication or identification	FRE 901
B	Best evidence rules prohibit introduction	FRE 1001-1002
C	Improper compilation of separate documents	FRE 403, 901
D	Improper designation (designation is neither a question or testimony)	FRE 401, 402
E	Improper examination (vague, ambiguous, loaded, leading, etc.)	FRE 402, 403, 602, 611
F	Lack of foundation/personal knowledge (including calls for speculation)	FRE 402, 403, 602, 611
H	Hearsay if offered for the truth of the matter asserted	FRE 801, 802
I	Incomplete document or testimony	FRE 106, 403
M	Offer or discussion for settlement or compromise	FRE 408
N	Exhibit not produced in discovery	FRE 403
O	Improper opinion testimony	FRE 701-704
P	Privileged or attorney work product	FRE 501, 502
R	Lack of relevance	FRE 401, 402
S	Summary requiring underlying data or information	FRE 1006
T	Beyond the scope of the Rule 30(b)(6) topic for which a witness has been designated	FRE 602, FRCP 30(b)(6)
U	Unduly prejudicial, wasteful, confusing, misleading or cumulative	FRE 403

EXHIBIT 9

Deposition of Kim T. Arndt December 21, 2018			
Defendants' Designation	Plaintiffs' Objections	Plaintiffs' Counter- Designation	Defendants' Objection to Counter- Designation
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52:8-15			
53:23-54:8			
55:15-16; 55:18-56:5			
58:8-22; 58:24-59:4; 59:6-17			
60:11-20			
61:23-62:2; 62:4-18			
67:12-13; 67:15-24; 68:2-69:7; 69:9-70:12; 70:18-71:3; 71:14-72:2; 72:7-23; 73:6-25; 74:7-9; 74:11-15; 76:12-17; 76:19; 76:21-23; 76:25-77:14; 77:16; 77:17-21; 77:23-78:14; 79:4-10; 79:16-17; 79:19-25; 80:2			
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105:17-106:19; 106:21-107:15; 107:17-25; 108:11-109:5; 109:7-14; 110:18-22; 110:24-111:9; 111:11-20; 111:23-112:8; 112:10-113:3			
118:21-25; 119:3-25; 120:3-21			
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Deposition of Kim T. Arndt December 21, 2018			
Defendants' Designation	Plaintiffs' Objections	Plaintiffs' Counter- Designation	Defendants' Objection to Counter- Designation
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160:5-6; 160:16- 161:2; 161:23- 162:11; 162:13-163:4		161:3-17	
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EXHIBIT 9

Deposition of Diane Boschelli November 30, 2018			
Defendants' Designation	Plaintiffs' Objections	Plaintiffs' Counter- Designation	Defendants' Objection to Counter- Designation
5:11-13			
14:16-25			
15:2-19; 15:21-22			
17:12-18:18; 18:25- 19:5; 22:13-23:4; 25:14-22; 27:21- 28:11; 28:13-29:12; 30:3-16; 32:5-10			
35:2-15; 36:3-14; 37:4-10; 37:14-38:8; 38:10-21; 38:23-39:7; 39:9-23			
43:7-44:3; 45:23- 46:2; 46:4-6; 47:24- 48:4; 48:11-14; 48:16-18; 48:20-23; 48:25-49:4; 49:6-7			
49:8-25; 50:15-19; 51:16-21; 51:23- 52:11; 52:13-23; 58:3-8			
66:7-19; 66:22-67:4; 67:6-68:6		62:24-63:7; 64:15-23	
68:22-69:10; 69:12- 14; 69:24-70:5; 70:23-71:8; 71:10- 72:3; 73:9-10; 73:12- 18; 73:22	Error - 69:24-70	72:4-6; 72:8-13	
74:4-74:18; 75:9-10; 75:12-16; 75:19-76:6; 76:8-17; 76:19-77:6; 78:6-7; 78:9-21; 78:23	I - 78:9-21		

EXHIBIT 9

Deposition of Nicholas Donato January 15, 2019			
Defendants' Designation	Plaintiffs' Objections	Plaintiffs' Counter- Designation	Defendants' Objection to Counter- Designation
7:6-15			
9:13-10:3; 10:14-11:9; 11:16-12:23;			
16:19-17:10; 17:23-18:14; 19:11-13; 19:15-20:6 20:14-21:3; 21:4-11; 22:6-23:16		15:25-16:18; 17:11-22; 18:15-19:10; 21:13-22:5; 23:17-23; 24:10-14; 24:19-23; 24:24-25:12; 25:19-26:2	
32:16-33:5; 38:7-39:7; 39:10-17; 41:23-42:4; 44:11-45:2		39:23-40:9; 41:3-16; 42:5-15; 43:18-20; 49:25-50:21	
53:8-25; 55:3-5; 56:1-16; 57:5-16		54:1-55:2	

EXHIBIT 9

Deposition of Brian Druker December 18, 2018			
Defendants' Designation	Plaintiffs' Objections	Plaintiffs' Counter-Designation	Defendants' Objection to Counter-Designation
5:24:6-2			
20:4-17; 21:16-22			
22:21-23:17			
27:13-28:5; 28:7-29:9		26:14-19; 26:24-27:7; 24:16-20; 28:2-4; 29:10-25	I (24:16-20) I (28:2-4)
30:22-31:8; 32:5-6; 32:8-19; 33:20-25		31:9-19; 33:1-9; 33:11-12; 33:16-25	
35:4-12; 35:14-15; 38:13-24; 54:1-22; 55:23-56:8;		53:13-21; 55:14-22	
71:18-72:20		73:13-20	
74:17-25; 75:17-20; 75:22-76:3; 76:12-77:13; 77:15-22; 78:21-79:15; 79:24-80:15		76:4-7; 77:23-25; 78:1-20; 79:16-18; 79:20-23; 80:16-21; 81:2-16	
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91:5-10; 92:7-9; 94:5-12; 94:20-95:16; 95:25-96:3; 96:5-12;		91:20-23; 91:25-92:2; 93:5-7; 93:9-19	
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128:18-130:14; 130:16-132:14; 132:16-134:7; 135:12-137:7; 137:9- 138:2; 138:6-12; 138:18-140:1			
154:13-155:7; 155:19-24; 156:25-157:10; 157:13-18; 157:20-24; 158:1	I	140:2-4; 140:23-141:8; 141:11-15; 143:16-23; 152:24-153:2; 153:9-19; 156:18-22	I (156:18-22)

EXHIBIT 9

Deposition of Gregg Feigelson December 12, 2018			
Defendants' Designation	Plaintiffs' Objections	Plaintiffs' Counter-Designation	Defendants' Objection to Counter-Designation
8:25-9:1			
12:20-13:18; 13:25-14:6; 14:11-21; 15:1-2;			
16:3-7; 16:17-24			
28:9-11			
32:4-20	I		
37:3-8			
38:9-11			
39:15-18			
41:13-14; 41:17-24			
43:12-23			
45:1-7			
47:14-16; 47:19-21; 47:23-48:4; 48:7-11			
49:25-50:3			
54:5-10; 54:25-55:4; 55:7; 55:9-10; 55:15-23; 56:1-10; 56:17-19; 56:22-57:4; 57:7; 57:17-19; 59:22-23; 60:1-4			
69:17-25; 74:2-9; 75:7-9; 75:12-18; 76:15-18; 76:21-24			
78:2-5; 78:8-16;			

EXHIBIT 9

Deposition of Gregg Feigelson December 12, 2018			
Defendants' Designation	Plaintiffs' Objections	Plaintiffs' Counter-Designation	Defendants' Objection to Counter-Designation
78:19-79:1			
83:4-8; 83:11-12			
85:8-12; 85:16-25; 86:18-20; 86:23			
88:15-89:1; 89:10-90:7; 94:7-25; 95:9-15; 95:18-24; 96:24-97:9; 98:23-99:5; 99:8-9			
118:9-119:1; 126:2-19; 126:22; 126:25-127:5; 127:16-128:22; 129:2-8; 129:11-131:4	I - 128:24-129:8; 129:11-131:4		
132:20-23; 133:1-16			
134:5-12; 134:17-135:24	Error - 137:17-135:24		
149:8-14; 150:7-14; 150:17; 152:7-16; 152:19-21			
209:16-210:15; 217:21-22; 217:25-218:10; 218:13-17			
221:7-24; 222:15-224:5; 224:12-22; 225:6-8; 225:10-11			
226:4-227:10; 227:16-25; 228:3-4			
230:6-23; 231:14-232:8; 232:11-12; 232:14-19; 232:22-25; 233:3-17			
234:2-24; 235:4-19; 235:22-24; 236:23-237: 8; 237:11-12			
237:24-239:5; 239:8; 239:17-23; 240:1-2			
240:17-241:19; 241:24-242:12; 242:15-16; 242:22-243:22			

EXHIBIT 9

Deposition of Gregg Feigelson December 12, 2018			
Defendants' Designation	Plaintiffs' Objections	Plaintiffs' Counter-Designation	Defendants' Objection to Counter-Designation
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247:23-249:11; 249:15-250:4; 250:7-12			
250:20-252:6; 252:9-10; 252:21-253:12; 253:15-16			
254:2-255:18; 255:21-22; 255:24-256:4			
256:14-257:23			
258:8-259:16; 259:19-20			
260:6-261:7			
262:5-263:13; 264:12-20; 264:23-265:16			

EXHIBIT 9

Deposition of James Gibbons January 9, 2019			
Defendants' Designation	Plaintiffs' Objections	Plaintiffs' Counter- Designation	Defendants' Objection to Counter- Designation
6:24-25; 7:4-8			
10:11-15; 13:3-9			
17:7-18:11	I		
24:25-26:15			
30:24-32:16; 34:25- 35:3; 35:9-36:8; 36:15-37:12; 37:15- 38:21; 38:23-39:8; 39:10-19; 40:8-25; 41:3-5; 41:7-10; 41:12-16; 41:18-22; 44:13-45:11		39:20-40:7	
45:20-46:13			
47:13-18; 47:22-48:5; 48:22-49:5; 49:15- 50:12; 51:16-53:4; 53:6-13; 54:18-55:7; 55:9-13; 55:15-19		55:22-25	
60:22-63:6; 63:14-18; 63:20-64:5; 64:7- 65:24; 66:5-20; 66:24-67:15; 68:20- 69:16; 69:25-70:6			
70:7-13; 70:21-71:3; 71:21-23; 72:6-20; 72:22-24; 73:2-74: 6; 74:8-9; 74:11-75:9; 76:10-77:22	I - 73:2-24	71:24-72:5	
77:23-78:24; 79:19- 23; 81:14-82:14; 82:16-83:2; 84:15- 86:9	Error - 77:23-76:24 I - 79:23-24; 81:14- 82:13		

EXHIBIT 9

Deposition of Jennifer Golas December 13, 2018			
Defendants' Designation	Plaintiffs' Objections	Plaintiffs' Counter- Designation	Defendants' Objection to Counter- Designation
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8:23-9:9			
10:23-11:2; 11:5-15; 15:22-25			
16:23-17:6; 20:22-25; 21:21-22:2			
23:6-16; 24:7-10; 25:14-26:3; 26:13-18; 27:9-16; 29:18-30:16; 30:19-31:15; 32:3-17; 33:7-34:6; 34:9-12; 36:16-37:11; 37:14- 21; 38:24-25; 39:4- 11; 39:14		28:3-13; 37:22-38:4	
39:15-40:2; 40:5-11; 40:14-41:22; 41:25- 42:10; 42:11-44:3; 44:6-45:15; 45:18- 46:2			
46:12-24; 47:21-50:5; 50:8-23; 51:23-52:2			
52:13-53:14; 53:22- 54:12; 56:2-11; 56:19-22		56:12-13; 56:16-18	
59:10-15; 59:22-60:8; 60:16-17; 60:20-61:4; 66:8-10; 66:13-19; 69:2-8; 77:2-3; 77:6- 19; 77:22-78:9; 79:4- 10; 79:13-16		78:12-17; 78:20-22	
80:10-15; 80:22-81:3; 81:16-20; 81:23-24; 82:4-6; 82:10-12; 82:15-83:2			
83:7-84:18; 90:11-20			

EXHIBIT 9

Deposition of Judy Lucas January 8, 2019			
Defendants' Designation	Plaintiffs' Objections	Plaintiffs' Counter- Designation	Defendants' Objection to Counter- Designation
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9:4-9			
21:2-24:5; 27:13- 28:13; 31:5-18		28:14-29:3	
40:2-21; 41:3-14; 42:6-11; 42:15-45:22; 45:25-46:17			
46:18-47:9			
51:6-20; 57:5-15; 61:4-12			
61:13-20; 62:10-17; 71:8-14; 71:17-72:5		62:18-25	
76:14-77:3; 81:19- 82:22; 83:4-6; 83:9- 20; 84:4-6; 84:9- 85:19; 87:22-88:12			
88:23-89:12; 90:10- 21; 92:5-94:13; 94:15-95:6; 95:9-10; 95:16-96:11; 96:21- 98:8; 98:11-17			
99:3-20; 102:23- 104:10			
104:14-105:15; 106:23-25; 107:4- 111:19; 115:8-20; 116:15-17			
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143:8-21; 144:3-11; 144:14-21; 144:24- 145:4; 146:2-3; 146:6-11; 146: 15; 150:6-151:2; 151:5- 20; 151:23-152:2		149:12-17 149:20-150:5	

EXHIBIT 9

Deposition of Judy Lucas January 8, 2019			
Defendants' Designation	Plaintiffs' Objections	Plaintiffs' Counter- Designation	Defendants' Objection to Counter- Designation
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EXHIBIT 9

Deposition of Henry Strong January 11, 2019			
Defendants' Designation	Plaintiffs' Objections	Plaintiffs' Counter-Designation	Defendants' Objection to Counter-Designation
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30:19-31:3; 31:5-15; 31:17-20			
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EXHIBIT 9

Deposition of Marc Tesconi April 10, 2019			
Defendants' Designation	Plaintiffs' Objections	Plaintiffs' Counter- Designation	Defendants' Objection to Counter- Designation
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13:13-24; 14:15-19; 15:9-15:21; 16:9-14; 17:13-18:3; 19:22- 20:15; 20:17-20; 21:13-16; 21:25-22:3; 22:15-19; 23:9-20; 23:23-24:3; 24:5; 24:7-11; 24:13-14; 24:16-25:1; 25:4-7; 26:14-27:4; 27:6; 27:10-28:1; 28:5-11	I - 26:14-27:4		
29:19-30:10; 31:8-14			
31:24-32:24			
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34:19-21; 34:23-35:1			
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35:16-36:4			
37:15-25			
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62:21-63:5; 66:10-22; 67:2-9			
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71:18-20; 71:22-72:1; 72:3-16; 72:18; 72:20-23; 72:25-74:3; 75:20-76:18			
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92:1-6; 92:11-18; 92:24-95:14; 95:21- 23			
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173:6-24; 180:13-23; 181:1-8; 181:11-24; 182:1-6; 182:9			
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215:17-216:13			
246:5-247:9; 250:21-251:21; 251:23-252:1			
256:18-257:9; 257:11-17; 257:19; 257:21-22			
270:7-25; 271:20-272:6; 272:16-20; 272:22-24			
288:5-25; 292:23-293:17; 293:19-294:2; 294:13-295:6			
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324:9-325:12			
327:19-328:8; 328:25-330:1		330:9-331:8	
332:25-333:19			
336:3-23			
339:23-341:24			
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348:16-349:13			
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EXHIBIT 9

Deposition of Hong Wen January 3, 2019			
Defendants' Designation	Plaintiffs' Objections	Plaintiffs' Counter-Designation	Defendants' Objection to Counter-Designation
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32:11-33:12			
35:19-36:17			
39:21-40:23; 41:8-12			
42:21-43:16; 43:18-24; 44:1-17			
62:17-63:17; 67:6-17; 67:19-69:5; 69:7-70:1			
74:5-76:5; 76:25-77:17; 78:4-5; 78:7-11		77:18-21 77:25-78:3	
80:9-81:4; 81:6-7			
85:7-9; 85:11-20; 85:22; 87:22-88:14; 88:16-18			
98:13-21; 99:2-3; 99:6-18; 100:9-102:10		100:2-8	
113:18-114:5; 114:16-20; 119:5-9			
132:12-15; 133:1-3; 134:9-12; 136:8-137:4; 148:21-150:21			
152:16-153:13			
159:19-160:14			
160:15-19; 160:23-161:1	I - 160:15-19		
161:2-5;	I - 170:7-11		

EXHIBIT 9

162:12-163:14; 163:16-24; 164:3-7; 164:9-23; 164:25-165:14; 165:16-25; 169:9-19; 170:6-11; 171:21-172:11			
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EXHIBIT 10

EXHIBIT 10

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH LLC, WYETH)	
PHARMACEUTICALS LLC, PF PRISM)	
C.V., PBG PUERTO RICO LLC and)	
PF PRISM IMB B.V.)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 16-1305 (RGA)
)	CONSOLIDATED
SUN PHARMACEUTICAL INDUSTRIES)	
LIMITED and SUN PHARMACEUTICAL)	
INDUSTRIES, INC.,)	
)	
Defendants.)	
)	
)	

PLAINTIFFS' TRIAL EXHIBIT LIST

EXHIBIT 10

Objection Key for Sun's Objections to Plaintiffs' Trial Exhibit List

Objection Code	Description	Basis
A	Requires authentication or identification	FRE 901
E	Improper expert testimony	FRE 104, 701, 702, 703; FRCP 26
F	Lack of foundation or personal knowledge	FRE 602, 901
H	Hearsay	FRE 801, 802, 805
I	Incomplete document	FRE 106, 403
N	Not produced in discovery	FRCP 37; FRE 403
U	Unduly prejudicial, confusing, wasteful, cumulative	FRE 403
R	Lack of relevance	FRE 402
ILL	Illegible	
DUP	Duplicative of other exhibits	

EXHIBIT 10

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 001	Ardnt Ex. 1	Curriculum vitae of Dr. Arndt		PFE-BOS01502593 - 97	F, R
PTX - 002		INTENTIONALLY LEFT BLANK (DUPE OF PTX-016)			Exhibit not provided
PTX - 003		INTENTIONALLY LEFT BLANK (DUPE OF PTX-150)			Exhibit not provided
PTX - 004	Ardnt Ex. 4; Boschelli, D. Ex. 38; Feigelson Ex. 7; Gibbons Ex. 2; Lindsley Ex. 15; Murcko Ex. E; Tesconi 15	Boschelli, D., Ye, F., Wang, Y., Dutia, M., Johnson, S., Wu, B., Miller, K., Powell, D., Yaczko, D., Young, M., Tischler, M., Arndt, K., Discafani, C., Etienne, C., Gibbons, J., Grod, J., Lucas, J., Weber, J. and Boschelli, F. (2001). Optimization of 4-Phenylamino-3-quinolinecarbonitriles as Potent Inhibitors of Src Kinase Activity. <i>J. Med. Chem.</i> 2001 44, 23, 3965-3977	5/21/2001		F, H
PTX - 005		INTENTIONALLY LEFT BLANK			
PTX - 006		INTENTIONALLY LEFT BLANK			
PTX - 007		INTENTIONALLY LEFT BLANK			
PTX - 008	Ardnt Ex. 8	Presentation - Kinases in Oncology	8/22/2002	PFE-BOS02664492 - 536	A, F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 009		INTENTIONALLY LEFT BLANK			
PTX - 010	Ardnt Ex. 10	E-mail from Kim Arndt to Frank Boschelli, Subject: reply to Darryl	2/13/2003	PFE-BOS01598733	F, H, U, R
PTX - 011	Ardnt Ex. 11	Summary of February 5, 2003, Src Kinase Program Discussion	2/12/2003	PFE-BOS01598734 - 38	F, H, U, R
PTX - 012	Ardnt Ex. 12	Memo describing Src Kinase program discussion on February 5	2/18/2003	PFE-BOS01532072 - 73	F, H, U, R
PTX - 013		INTENTIONALLY LEFT BLANK			
PTX - 014	Balaji Ex. 1	Plaintiff's Notice of Deposition of SK Balaji	11/27/2018	ECF 140	none
PTX - 015		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 016	Balaji Ex. 3; Dabre Ex. 3; Lindsley Ex. 1; Murcko Ex. A; Srivastava Ex. 5	U.S. Patent Number 7,417,148	8/26/2008	PFZFH0001198 - 208	none

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 017		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 018		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 019		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 020		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 021		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 022		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 023		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 024		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 025		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 026		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 027		INTENTIONALLY LEFT BLANK			Exhibit not

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
					provided
PTX - 028		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 029		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 030		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 031		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 032		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 033		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 034		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 035		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 036		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 037		INTENTIONALLY LEFT BLANK			Exhibit not provided

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 038		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 039		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 040		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 041	Boschelli, D. Ex. 30	Diane Harris Boschelli resume		PFE-BOS01585503 - 15	F, R
PTX - 042		INTENTIONALLY LEFT BLANK (DUPE OF PTX-016)			Exhibit not provided
PTX - 043	Boschelli, D. Ex. 33	Discovery Prioritization Process Program Updates		PFE-BOS01532210 - 11	F, H, U, R
PTX - 044	Boschelli, D. Ex. 34	Application for Discovery Team Status	1/25/2001	PFE-BOS02611765 - 77	F, H, U, R
PTX - 045	Boschelli, D. Ex. 35	Application for Team Status, Small Molecules - Pre-Development	9/23/2002	PFE-BOS02612069 - 82	F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 046	Boschelli, D. Ex. 36	Src Kinase Inhibitor - Oncology WAY-173606 Pre-Development, 9-23-02	9/23/2002	PFE-BOS01696030 - 61	A, F, H, U, R
PTX - 047	Boschelli, D. Ex. 37	Bosutinib: From Yeast to the Clinic		PFE-BOS01633993 - 4031	A, F, H, U, R
PTX - 048		INTENTIONALLY LEFT BLANK			
PTX - 049	Boschelli, D. Ex. 40	International Patent Publication Number WO 03/093242 A1	11/13/2003	SUN-BOS0012482 - 573	F, H
PTX - 050	Boschelli, F. Ex. 1; Feigelson Ex. 1	Defendants' Amended Notice of Deposition of Plaintiffs' Pursuant to Federal Rule Civil Procedure 30(b)(6)	11/20/2018	ECF 131	none
PTX - 051	Boschelli, F. Ex. 2; Feigelson Ex. 14	Plaintiffs' Responses and Objections to Defendants' Notice of Deposition Pursuant to Federal Rules Civil Procedure 30(b)(6)	11/9/2018		none
PTX - 052	Boschelli, F. Ex. 3	Copy of Frank Boschelli's curriculum vitae		PFE-BOS01773866 - 74	F, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 053	Boschelli, F. Ex. 6; Gibbons Ex. 3; Lucas Ex. 12	Email from: Boschelli, Frank to: Ye, Fei; Arndt, Kim; Boschelli, Diane; Etienne, Carlo; Frost, Philip; Gibbons, Jay; Lucas, Judy; Nardin, Danielle; Weber, Jennifer M. Subject: manuscript attached	5/20/2002	PFE-BOS01772244	A, F, H, U, R
PTX - 054	Boschelli, F. Ex. 7; Gibbons Ex. 4; Lucas Ex. 13	Email Attachment Draft manuscript - A 4-anilino-3-quinolinecarbonitrile dual inhibitor of Src and Abl kinases is a potent anti-proliferative agent against CML cells in culture and causes regression of K562 xenografts in nude mice		PFE-BOS01772245 - 73	A, F, H, U, R
PTX - 055		INTENTIONALLY LEFT BLANK			
PTX - 056		INTENTIONALLY LEFT BLANK			
PTX - 057		INTENTIONALLY LEFT BLANK			
PTX - 058		INTENTIONALLY LEFT BLANK			
PTX - 059		INTENTIONALLY LEFT BLANK			

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 060		INTENTIONALLY LEFT BLANK			
PTX - 061		INTENTIONALLY LEFT BLANK			
PTX - 062		INTENTIONALLY LEFT BLANK			
PTX - 063		INTENTIONALLY LEFT BLANK			
PTX - 064		INTENTIONALLY LEFT BLANK			
PTX - 065		INTENTIONALLY LEFT BLANK			
PTX - 066		INTENTIONALLY LEFT BLANK			

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 067	Ardnt Ex. 14; Boschelli, F. Ex. 25	Email chain Subject: Src inhibitors	10/14/2002	PFE-BOS01534204 - 05	A, F, H, U, R
PTX - 068	Ardnt Ex. 15; Boschelli, F. Ex. 26; Donato Ex. 2; Druker Ex. 12	Abstract - A dual Src/Abl kinase inhibitor causes regression of CML xenografts in nude mice. Frank Boschelli, Jennifer M. Goias, Kim Arndt, Carlo Etienne, Judy Lucas, Danielle Nardin, James Gibbons, Philip Frost, Fei Ye and Diane H. Boschelli. Dept. of Oncology and Chemical Sciences, Wyeth Research, 401 N. Middletown Rd., Pearl River, NY 10965		PFE-BOS01534206	F, H
PTX - 069	Boschelli, F. Ex. 27	Donato, et al., Novel Tyrosine Kinase Inhibitors Suppress BCR-ABL Signaling and Induce Apoptosis in STI-571 Sensitive and Resistant CML Cells, Blood 100:370a (2002)		SUN-BOS0012019 - 20	F, H
PTX - 070	Boschelli, F. Ex. 28; Nadkarni Ex. 36	Boschelli, D., Ye, F., Wang, Y., Dutia, M., Johnson, S., Wu, B., Miller, K., Powell, D., Yaczko, D., Young, M., Tischler, M., Arndt, K., Discafani, C., Etienne, C., Gibbons, J., Grod, J., Lucas, J., Weber, J. and Boschelli, F. (2001). Optimization of 4-Phenylamino-3-quinolinecarbonitriles as Potent Inhibitors of Src Kinase Activity.	5/21/2001	SUN-BOS0011849 - 61	F, H, DUP

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		Journal of Medicinal Chemistry, 44(23), pp.3965-3977.			
PTX - 071	Boschelli, F. Ex. 29; Wen 6	Golas JM, Arndt K, Etienne C, Lucas J, Nardin D, Gibbons J, Frost P, Ye F, Boschelli DH, Boschelli F. SKI-606, a 4-anilino-3-quinolinecarbonitrile dual inhibitor of Src and Abl kinases, is a potent antiproliferative agent against chronic myelogenous leukemia cells in culture and causes regression of K562 xenografts in nude mice. Cancer Res. 2003 Jan 15;63(2):375-81.	1/15/2003	PFE-BOS00252107 - 113	F, H
PTX - 072		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 073		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 074		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 075		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 076	Clarke Ex. 1	Defendants' Second Amended Notice of Deposition of Plaintiffs Pursuant to Fed. R.	12/12/2018	ECF 164	none

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		Civ. P. 30(b)(6)			
PTX - 077		INTENTIONALLY LEFT BLANK (DUPE OF PTX-016)			Exhibit not provided
PTX - 078		INTENTIONALLY LEFT BLANK			
PTX - 079		INTENTIONALLY LEFT BLANK			
PTX - 080		INTENTIONALLY LEFT BLANK			
PTX - 081		INTENTIONALLY LEFT BLANK			
PTX - 082	Dabre Ex. 1	Plaintiffs' Notice of Deposition of Rahul Dabre	11/27/2018	ECF 141	none
PTX - 083	Dabre Ex. 4	U.S. Patent Number 7,767,678	8/3/2010	PFZFH0001220 - 39	none
PTX - 084		INTENTIONALLY LEFT BLANK (DUPE OF PTX-017)			Exhibit not provided
PTX - 085		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 086		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 087		INTENTIONALLY LEFT BLANK			Exhibit not provided

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 088		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 089		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 090		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 091	Donato Ex. 1	Notice of Subpoena	12/27/2018	ECF 177	none
PTX - 092	Donato Ex. 3	Donato NJ, Wu JY, Stapley J, Gallick G, Lin H, Arlinghaus R, Talpaz M. <i>BCR-ABL independence and LYN kinase overexpression in chronic myelogenous leukemia cells selected for resistance to STI571</i> . Blood. 2003 Jan 15;101(2):690-8	1/15/2003		F, H, U, R
PTX - 093	Druker Ex. 1	Notice of Subpoena	12/4/2018		none
PTX - 094	Druker Ex. 2	Documents related to Request for Production 3: Agreements with Plaintiffs			F, H, U, R
PTX - 095	Druker Ex. 3	Documents related to Request for Production 1: Documents relating to bosutinib (SKI-606 or WAY-173606) created prior to November 6, 2003			F, H, U, R
PTX - 096	Druker Ex. 4	Documents related to Request for Production 2: All communications with			F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		Plaintiffs prior to November 6, 2003			
PTX - 097	Druker Ex. 5	Composite Exhibit Abstracts from Blood and emails			A, F, H, U, R, I
PTX - 098	Druker Ex. 8; Druker Ex. 9	Email from: Brian Druker to: Frank Boschelli (BOSHED@USPR01.WAPR12) Subject: Src inhibitors	10/8/2002	PFE-BOS02768294	A, F, H, U, R
PTX - 099		INTENTIONALLY LEFT BLANK (DUPE OF PTX-098)			Exhibit not provided
PTX - 100	Druker Ex. 10	Proposal to Wyeth from Druker attached to 10/13/2002 email	10/13/2002	PFE-BOS 02768298 - 99	A, F, H, U, R
PTX - 101	Druker Ex. 11	Email chain between Frank Boschelli, Brian Druker, Diane Bochelli, Philip Frost BCC: Kim Arndt Subject: Src inhibitors	10/14/2002	PFE-BOS 01611076 - 77	A, F, H, U, R
PTX - 102	Druker Ex. 13	Email chain between Frank Boschelli, Brian Druker, Diane Bochelli, Philip Frost Subject: Src inhibitors	10/18/2002	PFE-BOS01566859 -60	A, F, H, U, R
PTX - 103	Druker Ex. 14	Email chain between Brian Druker, Frank Boschelli, Paul LaRosee Subject: Material Transfer Agreement	7/8/2003	PFE-BOS02768289 -92	A, F, H, U, R
PTX - 104	Feigelson Ex. 2	Defendants' Amended Notice of	12/4/2018		none

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		Deposition of Gregg Feigelson			
PTX - 105	Feigelson Ex. 4; Tesconi 11; Wen 4	International Patent Publication Number WO 03/093242 A1	11/13/2003	Alembic_Wyeth0016035-126	
PTX - 106	Feigelson Ex. 5; Tesconi 14; Wen 5	Boschelli DH, Wang YD, Ye F, Wu B, Zhang N, Dutia M, Powell DW, Wissner A, Arndt K, Weber JM, Boschelli F. <i>Synthesis and Src kinase inhibitory activity of a series of 4-phenylamino-3-quinolinecarbonitriles</i> . J Med Chem. 2001 Mar 1;44(5):822-33.	9/29/2000	Alembic_Wyeth0015687-98	
PTX - 107	Feigelson Ex. 6; Tesconi 8	Golas JM, Arndt K, Etienne C, Lucas J, Nardin D, Gibbons J, Frost P, Ye F, Boschelli DH, Boschelli F. SKI-606, a 4-anilino-3-quinolinecarbonitrile dual inhibitor of Src and Abl kinases, is a potent antiproliferative agent against chronic myelogenous leukemia cells in culture and causes regression of K562 xenografts in nude mice. Cancer Res. 2003 Jan 15;63(2):375-81.	1/15/2003	Alembic_Wyeth0015721-28	
PTX - 108	Karpinski Ex. 13	Extended motifs from water and chemical functional groups in organic molecular crystals - Infantes, L. et al.	11/25/2003	Alembic_Wyeth0330590 - 96	A, F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 109		INTENTIONALLY LEFT BLANK			
PTX - 110	Feigelson Ex. 10	Laboratory Notebook - L23445		PFE-BOS02575275 - 486	A, F, H, U, R
PTX - 111	Feigelson Ex. 11	Laboratory Notebook - L27546		PFE-BOS02545487 - 690	A, F, H, U, R
PTX - 112		INTENTIONALLY LEFT BLANK			A, F, H, U, R
PTX - 113		INTENTIONALLY LEFT BLANK			
PTX - 114		INTENTIONALLY LEFT BLANK			
PTX - 115		INTENTIONALLY LEFT BLANK			
PTX - 116		INTENTIONALLY LEFT BLANK			
PTX - 117		INTENTIONALLY LEFT BLANK			
PTX - 118	Gibbons Ex. 5; Golas Ex. 9	Golas JM, Arndt K, Etienne C, Lucas J, Nardin D, Gibbons J, Frost P, Ye F, Boschelli DH, Boschelli F. SKI-606, a 4-anilino-3-quinolinecarbonitrile dual inhibitor of Src and Abl kinases, is a potent antiproliferative agent against chronic myelogenous leukemia cells in culture and causes regression of K562 xenografts in nude mice. Cancer Res. 2003 Jan	1/15/2003		F, H, DUP

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		15;63(2):375-81.			
PTX - 119	Golas Ex. 1	Jennifer M. (Weber) Golas CV			F, R
PTX - 120		INTENTIONALLY LEFT BLANK			
PTX - 121		INTENTIONALLY LEFT BLANK			
PTX - 122		INTENTIONALLY LEFT BLANK			
PTX - 123		INTENTIONALLY LEFT BLANK			
PTX - 124	Gramling Ex. 1	Defendants' Notice of Deposition of Plaintiffs Pursuant to Fed. R. Civ. P. 30(b)(6)	10/19/2018	ECF 109	none
PTX - 125		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 126	Gramling Ex. 3	License Agreement - 2011	11/30/2011	PFE-BOS00000018 - 50	A, F, H, U, R
PTX - 127	Gramling Ex. 4	Plaintiffs' Supplemental Objections and Responses to Defendants' Joint Interrogatories No. 9	1/7/2019		U, R
PTX - 128	Gramling Ex. 5	Contribution Agreement PF Prism C.V. to Pfizer Pharmaceuticals LLC Subject	11/22/2011	PFE-BOS00000001 - 05	A, F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		Matter: Bostinib			
PTX - 129	Gramling Ex. 6	License Agreement - 2017	9/7/2017	PFE-BOS02787310 - 25	A, F, H, U, R
PTX - 130	Gramling Ex. 7	Amendment to 2011 License Agreement	11/29/2012	PFE-BOS02787344 -346	A, F, H, U, R
PTX - 131	Gramling Ex. 8	License and Sublicense Novation Deed	3/28/2017	PFE-BOS00000006 - 17	A, F, H, U, R
PTX - 132		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 133	Gramling Ex. 10	Second Amendment to the License Agreement	7/7/2017	PFE-BOS02787289 - 09	A, F, H, U, R
PTX - 134		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 135		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 136		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 137		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 138		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 139		INTENTIONALLY LEFT BLANK			Exhibit not provided

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 140		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 141	Karpinski Ex. 7	U.S. Patent Number 8,343,984	1/1/2013		F, H, U, R ILL
PTX - 142	Karpinski Ex. 8	U.S. Patent Number 7,989,494	8/2/2011		F, H, U, R ILL
PTX - 143	Karpinski Ex. 9	U.S. Patent Number 9,181,215	11/10/2015		F, H, U, R, ILL
PTX - 144	Karpinski Ex. 10	PCT Application, International Publication No. WO 2006/063762 A1	6/22/2006		F, H, U, R
PTX - 145	Karpinski Ex. 11	U.S. Patent Number 8,486,930	7/16/2013		F, H, U, R, ILL
PTX - 146	Karpinski Ex. 12	Hydration in Organic Crystals: Prediction from Molecular Structure - Desiraju, G.	1/1/1991		F, H, U, R
PTX - 147	Karpinski Ex. 13	Extended motifs from water and chemical functional groups in organic molecular crystals - Infantes, L. et al.	11/25/2003	Alembic_Wyeth0330590 - 96	
PTX - 148		INTENTIONALLY LEFT BLANK			
PTX - 149	Karpinski Ex. 15	PolyCrystalLine Report	4/12/2019		F, H

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 150	Balaji Ex. 4; Lindsley Ex. 2; Murcko Ex. B; Srivastava Ex. 6	U.S. Patent Number 7,919,625	4/5/2011	PFZFH0001209 - 19	none
PTX - 151		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 152		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 153		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 154		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 155		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 156		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 157		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 158		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 159		INTENTIONALLY LEFT BLANK			Exhibit not provided

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 160		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 161		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 162		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 163	Lindsley Ex. 14	Curriculum vitae of Dr. Craig W. Lindsley			Exhibit not provided
PTX - 164	Lindsley Ex. 17	PCT patent application with international publication number WO03/013540 A1	2/20/2003		F, H
PTX - 165	Lindsley Ex. 37	Klejman et al., The Src Family Kinase Hck Couples BCR/ABL to STAT5 Activation in Myeloid Leukemia Cells, The EMBO Journal, 21, 5766-74 (2002)	9/3/2002	SUN-BOS0012218 - 26	F, H
PTX - 166	Lucas Ex. 1	Curriculum vitae of Judy Lucas		PFE-BOS01771581 - 84	F, R
PTX - 167		INTENTIONALLY LEFT BLANK (DUPE OF PTX-016)			Exhibit not provided
PTX - 168		INTENTIONALLY LEFT BLANK			
PTX - 169	Lucas Ex. 5	Update for Src	9/28/2000	PFE-BOS01531045 - 49	F, H, U, R
PTX - 170	Lucas Ex. 9	Relationship between growth inhibition & staging size		PFE-BOS02760555 - 61	A, F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 171		INTENTIONALLY LEFT BLANK			
PTX - 172	Lucas Ex. 11	Relative tumor charts		PFE-BOS02730857	A, F, H, U, R
PTX - 173	Lucas Ex. 14	SKI-606, a 4-Anilino-3-quinolinecarbonitrile Dual Inhibitor of Src and Abl Kinases, Is a Potent Antiproliferative Agent against Chronic Myelogenous Leukemia Cells in Culture and Causes Regression of K562 Xenografts in Nude Mice	1/15/2003		F, H
PTX - 174	Mathur Ex. 42	Statements of certification under section 505(j)(2)(A)(vii) AND 21 CFR 314.94(a)(12)	8/30/2016	SUN-BOS0043563 - 68	Exhibit not provided
PTX - 175	Mathur Ex. 43	Document entitled, "Strategic Note, bosutinib tablets 100 milligrams and 500 milligrams."		SUN-BOS0082038 - 40	Exhibit not provided
PTX - 176	Mathur Ex. 44	Regulatory Expectations Document		SUN-BOS0081749 - 53	Exhibit not provided
PTX - 177	Mathur Ex. 46	2/1/19 Letter, a submission to a minor complete response amendment for ANDA 209577, which is bosutinib tablets 100 and 500 milligrams	2/1/2019	SUN-BOS0089501 - 3	Exhibit not provided
PTX - 178	Mathur Ex. 48	Table of Contents, Annexure-1 containing XRD overlays of different batches		SUN-BOS0089448 - 93	Exhibit not provided

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 179	Mathur Ex. 5; Nadkarni Ex. 5	Form 356H Document for ANDA 209577	9/6/2016	SUN-BOS0084425 - 29	Exhibit not provided
PTX - 180	Mathur Ex. 6; Nadkarni Ex. 6	Statements of certifications under section 505(j)(2)(A)(vii) AND 21 CFR 314.94(a)(12)	8/19/2017	SUN-BOS0089229 - 36	Exhibit not provided
PTX - 181		INTENTIONALLY LEFT BLANK (DUPE OF PTX-016)			Exhibit not provided
PTX - 182		INTENTIONALLY LEFT BLANK			
PTX - 183	Mathur Ex. 12; Nadkarni Ex. 12	Quality Overall Summary For Bosutinib Tablets		SUN-BOS0013179 - 343	Exhibit not provided
PTX - 184	Mathur Ex. 16; Nadkarni Ex. 16	3.2.S.1.3. General Properties		SUN-BOS0016165 - 66	Exhibit not provided
PTX - 185	Mathur Ex. 19; Nadkarni Ex. 19	Minutes of Product Review Meeting	5/24/2016	SUN-BOS0084327 - 30	Exhibit not provided
PTX - 186	Mathur Ex. 20; Nadkarni Ex. 20	Bosutinib Monohydrate (Form-I) MSN Laboratories Private Limited Information		SUN-BOS0082075 - 76	Exhibit not provided
PTX - 187	Mathur Ex. 21; Nadkarni Ex. 21	Bosutinib Monohydrate (Form-I) MSN Laboratories Private Limited Information		SUN-BOS0082092 - 119	Exhibit not provided
PTX - 188	Mathur Ex. 22; Nadkarni Ex. 22	Bosutinib Monohydrate (Form-I) MSN Laboratories Private Limited Information		SUN-BOS0082974 - 3000	Exhibit not provided

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 189	Mathur Ex. 24; Nadkarni Ex. 24	Bosutinib Tablets Correspondence	5/7/2016	SUN-BOS0040769 - 72	Exhibit not provided
PTX - 190	Mathur Ex. 25; Nadkarni Ex. 25	Document Revision 2015-09-25	3/14/2016	SUN-BOS0041474 - 76	Exhibit not provided
PTX - 191	Mathur Ex. 26; Nadkarni Ex. 26	Document, Information Request issued by US FDA related to ANDA 209577	4/4/2017	SUN-BOS0025648 - 52	Exhibit not provided
PTX - 192	Mathur Ex. 27; Nadkarni Ex. 27	Document entitled "Quality Response to information request dated April 04, 2017."	4/4/2017	SUN-BOS0043277 - 93	Exhibit not provided
PTX - 193	Mathur Ex. 29; Nadkarni Ex. 29	Document entitled "Response to ANDA deficiency comments received from Sun Pharmaceutical Industries Limited for Bosutinib Route Code BS,"	4/1/2017	SUN-BOS0034009 - 131	Exhibit not provided
PTX - 194	Mathur Ex. 30; Nadkarni Ex. 30	FDA November 29, 2017 Complete Response Letter to Sun	11/29/2017	SUN-BOS0088869 - 74	Exhibit not provided
PTX - 195	Mathur Ex. 31; Nadkarni Ex. 31	Response to a complete response letter dated November 29, 2017, for the product bosutinib tablets, 100 mg and 500 mg, ANDA 209577	11/29/2017	SUN-BOS0088991 - 96	Exhibit not provided
PTX - 196	Mathur Ex. 32; Nadkarni Ex. 32	Sun's Annexure-2 PXRD Diffractograms of Batch Nos. BOST/D410/9S/05, BS0021215, BS0031215, and BS0010116		SUN-BOS0088783 - 96	Exhibit not provided
PTX - 197	Mathur Ex. 33;	Sun's XRPD Diffractograms and Raw Data of Sample Batches of Sun's ANDA		SUN-BOS0024859 - 977	Exhibit not

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
	Nadkarni Ex. 33	Product			provided
PTX - 198		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 199	Murcko Ex. C	Curriculum Vitae of Mark A. Murcko Ph.D.	5/11/2019		F, R
PTX - 200	Murcko Ex. D	Donato, et al., Use of c-Src Inhibitors Alone or in Combination with STI571 for the Treatment of Leukemia, WO 03/013540	2/20/2003		F, H, DUP
PTX - 201		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 202	Murcko Ex. G	Murcko Materials Considered			F, H, U, R
PTX - 203	Murcko Ex. K	Mark M. Moasser et al., Inhibition of Src Kinases by a Selective Tyrosine Kinase Inhibitor Causes Mitotic Arrest, 56 Cancer Res. 6145 (1999)	12/15/1999		F, H, U, R
PTX - 204	Murcko Ex. M	Yi Liu et al., Structural Basis for Selective Inhibition of Src Family Kinases by PP1, 6 Chemistry & Biology 671 (1999)	8/13/1999		F, H, U, R
PTX - 205	Lindsley Ex. 19; Murcko Ex. O	Warmuth et al., The Src Family Kinase Hck Interacts with Bcr-Abl by a Kinase-Independent Mechanism and	12/26/1997	SUN-BOS0012434 - 45	F, H

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		Phosphorylates the Grb2-Binding Site of Bcr, J. Biol. Chem. 272(52):33260-33270 (1997)			
PTX - 206	Murcko Ex. P	Druker BJ et al, Chronic Myelogenous Leukemia, 1 Hematology 111 (2002)			F, H, U, R
PTX - 207	Murcko Ex. Q	Druker BJ et al., Effects of a Selective Inhibitor of the Abl Tyrosine Kinase on the Growth of Bcr-Abl Positive Cells, 2 Nature Med. 561 (1996)	5/1/1996		F, H, U, R
PTX - 208	Murcko Ex. R	Hanke JH et al., Discovery of a Novel, Potent, and Src Family-selective Tyrosine Kinase Inhibitor 271 J. Biological Chemistry 695 (1996)	1/12/1996		F, H, U, R
PTX - 209	Murcko Ex. S	Dorsey JF et al., The Pyrido[2,3-dipyrimidine Derivative PD180970 Inhibits P210Bcr-Abl Tyrosine Kinase and Induces Apoptosis of K562 Leukemic Cells, 60 Cancer Res. 3127 (2000)	6/15/2000		F, H, U, R
PTX - 210	Lindsley Ex. 35; Murcko Ex. U	Nimmanapalli et al., Molecular Characterization and Sensitivity of STI571 (Imatinib Mesylate, Gleevec)-resistant, Bcr-Abl-Positive, Human Acute Leukemia Cells to SRC Kinase Inhibitor PD180970 and 17-Allylamino-17-Demethoxygeldanamycin, Cancer Res.	10/15/2002	SUN-BOS0012233 - 42	F, H

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		62:5761-5769 (2002)			
PTX - 211	Murcko Ex. V	Bhushan Nagar et al., Crystal Structures of the Kinase Domain of c-Abl in Complex with the Small Molecule Inhibitors PD173955 and Imatinib (STI-571) 62 Cancer Res. 4236 (2002)	8/1/2002		F, H, U, R
PTX - 212	Lindsley Ex. 33; Murcko Ex. W	David Wisniewski et al., Characterization of Potent Inhibitors of the Bcr-Abl and the c-Kit Receptor Tyrosine Kinases, 62 Cancer Research 4244 (2002)	8/1/2002		F, H, U, R
PTX - 213	Murcko Ex. Z	Fahad A. Al-Obeidi & Kit S. Lam, Development of Inhibitors for Protein Tyrosine Kinases, 19 Oncogene 5690 (2000)			F, H, U, R
PTX - 214	Murcko Ex. AA	Thomas Schindler et al., Structural Mechanism for STI-571 Inhibition of Abelson Tyrosine Kinase, 289 Science 1938 (2000)	9/15/2000		F, H, U, R
PTX - 215	Murcko Ex. BB	Blake RA et al., SU6656, a Selective Src Family Kinase Inhibitor, Used to Probe Growth Factor Signaling, 20 Molecular & Cellular Biology 9018 (2000)	9/7/2000		F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 216	Lindsley Ex. 39; Murcko Ex. CC	Jiirg Zimmerman et al., Potent and Selective Inhibitors of the Abl-Kinase: Phenylaminopyrimidine (PAP) Derivatives, 7 Bioorganic & Med. Chemistry Letters 187 (1997)	12/11/1996		F, H, U, R
PTX - 217	Murcko Ex. DD	Uwe Trinks et al., Dianilinophthalimides: Potent and Selective, ATP-Competitive Inhibitors of the EGF-Receptor Protein Tyrosine Kinase, J.Med. Chem 1994, 37, 1015-1027	9/24/1993		F, H, U, R
PTX - 218	Murcko Ex. EE	Peter Traxler et al., Use of Pharmacophore Model for the Design of EGF-R Tyrosine Kinase Inhibitors 4-Phenylaminopyrazolo djpyrimidines, J.Med Chem 1997, 40, 3601 - 3616	3/3/1997		F, H, U, R
PTX - 219	Murcko Ex. FF	Missbach M et al., Substituted 5,7-Diphenyl-pyrrolo[2,3d]pyrimidines: Potent Inhibitors of the Tyrosine Kinase c-Src, Bioorganic & Medicinal Chemistry Letters 10 (2000) 945-949	2/22/2000		F, H, U, R
PTX - 220	Murcko Ex. GG	Altmann E. et al., 7-Pyrrolidinyl- and 7-Piperidinyl-5-wyl-pyrrolo[2,341-pyrimidines--Potent Inhibitors of the Tyrosine Kinase c-Src, 11 Biorganic & Med. Chemistry Letters 853, (2001)	2/2/2001		F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 221	Murcko Ex. HH	Leo Widler et al., 7-Alkyl- and 7-Cycloalkyl-5-aryl-pyrrolo[1,2,3-d]pyrimidines—Potent Inhibitors of the Tyrosine Kinase c-Src, 11 Biorganic & Med. Chemistry Letters 849 (2001)	2/2/2001		F, H, U, R
PTX - 222	Murcko Ex. II	Michael J. Mauro & Brian J. Druker, STI571: Targeting BCR-ABL as Therapy for CML, 6 Oncologist 233 (2001)	5/11/2001		F, H, U, R
PTX - 223	Murcko Ex. JJ	Gleevec Final Printed Labeling, Ctr. for Drug Evaluation & Research (2001)	5/9/2001		F, H, U, R
PTX - 224		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 225		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 226	Nadkarni Ex. 1	Plaintiffs' Notice of Deposition of Bharati Nadkarni	11/27/2018		none
PTX - 227	Nadkarni Ex. 3	Plaintiffs' Notice of Deposition of Sun Pharmaceutical Industries Limited and Sun Pharmaceutical Industries, Inc., Pursuant to Fed R. CIV P.30(b)(6)	11/26/2018		none
PTX - 228	Nadkarni Ex. 4	Work Address			F, H, U, R
PTX - 229		INTENTIONALLY LEFT BLANK			Exhibit not

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		(DUPE OF PTX-083)			provided
PTX - 230		INTENTIONALLY LEFT BLANK (DUPE OF PTX-150)			Exhibit not provided
PTX - 231		INTENTIONALLY LEFT BLANK (DUPE OF PTX-182)			Exhibit not provided
PTX - 232	Nadkarni Ex. 11	Bosutinib Tablets Labels	4/7/2016	SUN-BOS0024670 - 71	F, H, U, R
PTX - 233	Nadkarni Ex. 13	Errata 1 to development report	9/1/2016	SUN-BOS0000561 - 636	F, H, U, R
PTX - 234	Nadkarni Ex. 14	Sun's Clinical Study Report, titled "A Study to Evaluate the Relative Bioavailability of a Test Formulation of Bosutinib 100 mg Tablets (Sun Pharmaceutical Industries Limited, India) compared to Bosulif® (bosutinib monohydrate) Tablets [EQ 100 mg bosutinib] (PfizerLabs) in Healthy Adult Subjects under Fasted Conditions"	8/1/2016	SUN-BOS0004030 - 107	F, H, U, R
PTX - 235	Nadkarni Ex. 15	Sun's Clinical Study Report, titled "A Study to Evaluate the Relative Bioavailability of a Test Formulation of Bosutinib 100 mg Tablets (Sun Pharmaceutical Industries Limited, India) compared to Bosulif® (bosutinib monohydrate) Tablets [EQ 100 mg bosutinib] (Pfizer	7/26/2016	SUN-BOS0004663 - 738	F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		Labs) in Healthy Adult Subjects under Fed Conditions"			
PTX - 236	Nadkarni Ex. 17	Control of Drug Substance of Bosutinib	1/28/2016	SUN-BOS0016179 - 86	F, H, U, R
PTX - 237	Nadkarni Ex. 18	Structure elucidation of Reference standard Form S	3/2/2016	SUN-BOS0032408 - 34	F, H, U, R
PTX - 238	Nadkarni Ex. 23	Sun's Regulatory Expectations Document	12/11/2015	SUN-BOS0033581 - 85	F, H, U, R
PTX - 239	Nadkarni Ex. 28	Sun's Response to FDA Information Request		SUN-BOS0025024 - 38	F, H, U, R
PTX - 240	Nadkarni Ex. 34	Submission of response to GDUFA DMF COMPLETE RESPONSE Letter dated March 05, 2018 as eCTD submission through FDA electronic submission gateway as Amendment-IV.	4/12/2018	SUN-BOS0088777 - 82	F, H, U, R
PTX - 241	Nadkarni Ex. 35	Raw Material - Analytical Test Procedure	7/31/2018	SUN-BOS0088619 - 70	F, H, U, R
PTX - 242	Nadkarni Ex. 37	Notice of Paragraph IV Certification Regarding E.S. Patent No, 7,767,678	11/14/2016	PFE-BOS02601183 - 203	F, H, U, R
PTX - 243	Nadkarni Ex. 38	Notice of Paragraph IV Certification Regarding E.S. Patent Nos. 7,417,148 and 7,919,625	8/16/2017	PFE-BOS02601157 - 82	F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 244	Nadkarni Ex. 39	Production of Bosutinib Samples Pursuant to Offer of Confidential Access	12/15/2016		F, H, U, R
PTX - 245	Nadkarni Ex. 40	Production of Samples Pursuant to Protective Order	9/26/2018		F, H, U, R
PTX - 246	Nadkarni Ex. 41	Regional Information (Bosutinib Tablets 100 mg and 500 mg)		SUN-BOS0074220 - 28	F, H, U, R
PTX - 247		INTENTIONALLY LEFT BLANK			
PTX - 248		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 249		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 250		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 251		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 252		INTENTIONALLY LEFT BLANK (DUPE OF PTX-025)			Exhibit not provided
PTX - 253		INTENTIONALLY LEFT BLANK (DUPE OF PTX-024)			Exhibit not provided
PTX - 254		INTENTIONALLY LEFT BLANK			Exhibit not provided

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 255		INTENTIONALLY LEFT BLANK (DUPE OF PTX-026)			Exhibit not provided
PTX - 256		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 257		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 258		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 259		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 260		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 261		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 262		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 263		INTENTIONALLY LEFT BLANK			
PTX - 264		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 265		INTENTIONALLY LEFT BLANK			Exhibit not provided

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 266		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 267	Strong Ex. 2	Email from Tesconi to Clarke 9 et al.	6/25/2003	PFE-BOS01865456	A, F, H, U, R
PTX - 268	Strong Ex. 4	Email from Ku to Hadfield and Strong	6/30/2003	PFE-BOS02697233	A, F, H, U, R
PTX - 269	Strong Ex. 5	Laboratory Notebook - L23263	9/28/2001	PFE-BOS02591297	A, F, H, U, R
PTX - 270	Strong Ex. 6	Laboratory Notebook - L27384	8/31/2007	PFE-BOS02591593 - 804	A, F, H, U, R
PTX - 271	Tesconi 1	Defendants' Amended Notice of Deposition of Marc Safler Tesconi	4/2/2019	ECF 202	none
PTX - 272	Tesconi 2	Defendants' Third Amended Notice of Deposition of Plaintiffs' Pursuant to Fed. R. Civ. P. 30(b)(6)	4/2/2019		none
PTX - 273	Tesconi 7	Email with attachments from: Boschelli, Frank to: Ye, Fei; Arndt, Kim; Boschelli, Diane; Etienne, Carlo; Frost, Philip; Gibbons, Jay; Lucas, Judy; Nardin, Danielle; Weber, Jennifer M. Subject: manuscript attached	5/20/2002	PFE-BOS01772244 -73, PFE-BOS01772279 -80, PFE-BOS01772290	A, F, H, U, R
PTX - 274	Tesconi 9	Plaintiffs' Second Supplemental Objections and Response to Defendants' Interrogatory No. 1	1/11/2019		U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 275	Tesconi 10	Email - From Anthony Hadfield To: Beth Rasmussen CC: David Blum; Greg Feigelson; Anthony Hadfield; Sherry Ku; Michael K. O'Brien; Marc Tesconi Subject: Src Kinase WAY-173606	8/22/2002	PFE-BOS01754411	A, F, H, U, R
PTX - 276	Tesconi 12	Tieger, E., Kiss, V., Pokol, G., Finta, Z., Rohlíček, J., Skořepová, E. and Dušek, M., 2016. Rationalization of the formation and stability of bosutinib solvated forms. CrystEngComm, 18(48), 9260-74.	11/3/2016		F, H
PTX - 277	Tesconi 13	Bowles P, Frank R. Busch, Kyle R. Leeman, Andrew S. Palm, and Karen Sutherland, <i>Confirmation of Bosutinib Structure; Demonstration of Controls To Ensure Product Quality</i> . Organic Process Research & Development 2015 19 (12), 1997-2005	7/31/2015		A, F, H, U, R
PTX - 278	Tesconi 16	Laboratory Notebook - L23540		PFE-BOS02554109 - 321	A, F, H, U, R
PTX - 279	Tesconi 17	Laboratory Notebook - L23541		PFE-BOS02554322 - 534	A, F, H, U, R
PTX - 280	Tesconi 18	Laboratory Notebook - L24462		PFE-BOS02554831 - 5041	A, F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 281	Tesconi 19	Laboratory Notebook - L24465		PFE-BOS02555042 - 253	A, F, H, U, R
PTX - 282	Tesconi 20	Laboratory Notebook - L28411		PFE-BOS02591805 - 2018	A, F, H, U, R
PTX - 283	Tesconi 21; Wen 12	Laboratory Notebook - L24711		PFE-BOS02594300 - 510	A, F, H, U, R
PTX - 284		INTENTIONALLY LEFT BLANK			
PTX - 285	Tesconi 23; Wen 9	Technical Memo - Polymorph Study of SRC Kinase Inhibitor Way-173606	1/10/2004	PFE-BOS01850858 -68	F, H, U, R
PTX - 286	Tesconi 33	Publication Presentation Approval	11/6/2002	PFE-BOS02613006 - 07	A, F, H, U, R
PTX - 287	Tesconi 34	Publication Presentation Approval	7/9/2002	PFE-BOS02612930 - 31	A, F, H, U, R
PTX - 288		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 289		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 290		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 291	Trout 3	Guide for the Care and Use of Laboratory Animals: Eight Edition	7/3/1905		F, H, U, R
PTX - 292	Wen 1	Notice of Service of Subpoena	12/27/201	ECF 175	none

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
			8		
PTX - 293	Wen 2	Defendants' Amended Notice of Deposition of Hong Wen	1/2/2019	ECF 180	none
PTX - 294	Wen 8	SKI-606 Chemical Development Status	6/1/2005	PFE-BOS01680541 - 46	F, H, U, R
PTX - 295	Wen 10	Above and Beyond Award Nomination	6/3/2004	PFE-BOS01754033 - 35	F, H, U, R
PTX - 296	Wen 11	Laboratory Notebook - L24710		PFE-BOS02594088 - 299	A, F, H, U, R
PTX - 297	Wen 13	Laboratory Notebook - L26019		PFE-BOS02593975 - 4087	A, F, H, U, R
PTX - 298	Wen 14	Email From: hong wen To: KUS CC: TesconM; Ku Sherry Subject: Two drafts -- hydration/dehydration, polymorph	11/25/2009	PFE-BOS01856949	A, F, H, U, R
PTX - 299		INTENTIONALLY LEFT BLANK			
PTX - 300		INTENTIONALLY LEFT BLANK			
PTX - 301		INTENTIONALLY LEFT BLANK			
PTX - 302		INTENTIONALLY LEFT BLANK			

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 303		Email - From: Michael Bolt To: Chiarello, Dolores; Elliott, Janet; Hammons, Jeff; Kuhn, Tessa; Marsh, Billie; Mousseau, Sheila; Rice, Debra; Semeraro, Dulcie CC: Batastini, Geary; Clarke, David W.; Kirchner, Fred; Rasmussen, Beth Subject: Src Kinase in dogs (Way-173606)	4/1/2003	PFE-BOS02788705	A, F, H, U, R
PTX - 304		ACUF Amendment Form	4/1/2003	PFE-BOS02789098 - 135	A, F, H, U, R
PTX - 305		Medical Treatment Summary	4/1/2003	PFE-BOS02788139 - 40	A, F, H, U, R
PTX - 306		Multiple Dose Oral Ranging Study in Rats	9/8/2003	PFE-BOS02787292 - 316	A, F, H, U, R
PTX - 307		Multiple Dose Oral Ranging Study in Female Dogs\	1/29/2004	PFE-BOS02788145 - 63; PFE-BOS02788134	A, F, H, U, R
PTX - 308		Src Kinase Inhibitor- Oncology WAY- 173606 - Development Track Endorsement	6/26/2003	PFE-BOS01563261 - 318	A, F, H, U, R
PTX - 309		Src Kinase Inhibitor- Oncology WAY- 173606 - Development Track Recommendation		PFE-BOS02637289 - 305	A, F, H, U, R
PTX - 310		Notebook L21987		PFE-BOS02789276 - 489	A, F, H, U, R
PTX - 311		File History 10980097		PFZFH00000002 -473	A, F, H, U, R
PTX - 312		678 patent file history certificate		PFZFH0000474	I

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 313		File History 11478216 (678 patent)		PFZFH0000475 - 1020	A, F, H, U, R
PTX - 314		625 patent file history certificate		PFZFH0001021	I
PTX - 315		File History 12139834 (625 patent)		PFZFH0001022 - 197	A, F, H, U, R
PTX - 316		INTENTIONALLY LEFT BLANK (DUPE OF PTX-083)			Exhibit not provided
PTX - 317		Terminal Disclaimer 148 Patent		PFZFH0001240 - 48	F, H, U, R
PTX - 318		Email from: Feigelson to: Tesconi	5/19/2003	PFE-BOS01852421	A, F, H, U, R
PTX - 319		INTENTIONALLY LEFT BLANK			
PTX - 320		SKI-606 Oncology GDT Recommendation CML Indication	10/16/2003	PFE-BOS01611715 - 18	F, H, U, R
PTX - 321		INTENTIONALLY LEFT BLANK			
PTX - 322		Notebook L24831		PFE-BOS02789490 - 706	A, F, H, U, R
PTX - 323		Src Kinase Inhibitor - Oncology WAY-173606 Pre-Development (slides)	9/23/2002	PFE-BOS02662427	A, F, H, U, R
PTX - 324		Application for Team Status, Small Molecules - Pre-Development	9/23/2002	PFE-BOS02651518	F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 325		INTENTIONALLY LEFT BLANK			
PTX - 326		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 327		Leonard J. Chyall - CV			F, R
PTX - 328		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 329		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 330		Eszter Tieger et al., Rationalization of the Formation and Stability of Bosutinib Solvated Forms, 18 CrystEngComm. 9260 (2016)	2016		F, H, DUP
PTX - 331	Mathur Ex. 45	FDA October 29, 2018 Complete Response Letter to Sun	10/29/2018	SUN-BOS0089496 - 500	F, H, U, R
PTX - 332		FMC BioPolymer Certificate of Analysis, AcDiSol® Croscarmellose Sodium NF, Lot No. T1152C		SUN-BOS0001134 - 39	F, H, U, R
PTX - 333		FMC BioPolymer Certificate of Analysis, Avicel® Microcrystalline Cellulose NF, Lot No. 61207C		SUN-BOS0014378 - 83	F, H, U, R
PTX - 334		FMC BioPolymer Certificate of Analysis, Avicel® Microcrystalline Cellulose NF,		SUN-BOS0014417 - 22	Exhibit not

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		Lot No. 71511C			provided
PTX - 335		Pawley GS, Unit-cell Refinement From Powder Diffraction Scans, 14 J. Applied Crystallography 357 (1981)			F, H, U, R
PTX - 336		Ivanisevic I et al., Uses of X-Ray Powder Diffraction In the Pharmaceutical Industry (Shayne C. Gad ed., 2010)			F, H, U, R
PTX - 337		Haleblian JK, Characterization of Habits and Crystalline Modification of Solids and Their Pharmaceutical Applications, 64 J. Pharm. Sci. 1269 (1975)			F, H, U, R
PTX - 338		INTENTIONALLY LEFT BLANK			
PTX - 339		INTENTIONALLY LEFT BLANK			
PTX - 340		MSN Laboratories Private Limited's 3.2.S.3 Characterization		SUN-BOS0010905 - 35	A, F, H, U, R
PTX - 341		MSN Laboratories Private Limited's 3.2.S.4 Control of Drug Substance		SUN-BOS0027246 - 73	Exhibit not provided
PTX - 342		MSN Laboratories Private Limited's Certificate of Analysis, Bosutinib, Batch No. BS0021215		SUN-BOS0003718 - 26	Exhibit not provided
PTX - 343		INTENTIONALLY LEFT BLANK			

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		(DUPE OF PTX-399)			
PTX - 344		INTENTIONALLY LEFT BLANK (DUPE OF PTX-400)			
PTX - 345		Overlay plot of the XRPD pattern provided in Fig. 1, Pattern A of US Patent No. 7,767,678 with the XRPD pattern for 100 mg Sun's ANDA Product Batch No. GKR0162B obtained by SSCI			F, H, U, R, I
PTX - 346		INTENTIONALLY LEFT BLANK (DUPE OF PTX-197)			Exhibit not provided
PTX - 347		INTENTIONALLY LEFT BLANK (DUPE OF PTX-178)			
PTX - 348		Overlay plot of the XRPD pattern provided in Fig. 1, Pattern A of US Patent No. 7,767,678 with the XRPD pattern for 500 mg Sun's ANDA Product Batch No. GKR0165B obtained by SSCI			A, F, H, U, R
PTX - 349		Overlay plot of the XRPD pattern provided in Fig. 1, Pattern A of US Patent No. 7,767,678 with the XRPD pattern for Pfizer's sample of Form I bosutinib API obtained by SSCI			A, F, H, U, R
PTX - 350		INTENTIONALLY LEFT BLANK			Exhibit not

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
					provided
PTX - 351		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 352		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 353		INTENTIONALLY LEFT BLANK (DUPE OF PTX-313)			
PTX - 354		Report of Richard B. McClurg, Ph.D., titled "Characterization of Sun Pharmaceutical Bosutinib Products"			F, H, U, R
PTX - 355		Chipera SJ & David L. Bish, Fitting Full X-Ray Diffraction Patterns for Quantitative Analysis: A Method for Readily Quantifying Crystalline and Disordered Phases, 3 Advances in Materials Physics and Chemistry 47 (2013)	2013		F, H, U, R
PTX - 356		Sun's ANDA Module 1.14.1.5 Labeling History Question Based Review		SUN-BOS0000066 - 77	Exhibit not provided
PTX - 357		Sun's ANDA Module 2.3 Quality Overall Summary		SUN-BOS0000251 - 415; SUN-BOS0013179 - 343	F, H, U, R
PTX - 358		Sun's ANDA Module 3.2.P Drug Product		SUN-BOS0000481 - 88	Exhibit not provided

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 359		Sun's ANDA Module 3.2.P.2 Pharmaceutical Development		SUN-BOS0000491 - 98	F, H, U, R
PTX - 360		Sun's ANDA Module 3.2.P.3 Manufacture		SUN-BOS0000682 -84	F, H, U, R, I
PTX - 361		Sun's ANDA Module 3.2.P.3.2 Batch Formula		SUN-BOS0000685 - 88	A, F, H, U, R
PTX - 362		Sun's ANDA Module 3.2.P.3.3 Description of Manufacturing Process and Process Controls		SUN-BOS0000689 -91	A, F, H, U, R, ILL
PTX - 363		Sun's ANDA Module 3.2.P.3.4 Controls of Critical Steps and Intermediaries		SUN-BOS0000692	F, R
PTX - 364		Sun's ANDA Module 3.2.P.3.5 Process Validation and/or Evaluation		SUN-BOS0000693	Exhibit not provided
PTX - 365		Sun's ANDA Module 3.2.P.4 Control of Excipients Croscarmellose Sodium NF (AC-DI-SOL)		SUN-BOS0001071	Exhibit not provided
PTX - 366		Sun's ANDA Module 3.2.R Regional Information (Bosutinib Tablets 100 mg and 500 mg)		SUN-BOS0002126 - 134	F, H
PTX - 367		Sun's ANDA Module 3.2.S.1.3 General Properties		SUN-BOS0003016 - 17	F, H
PTX - 368		INTENTIONALLY LEFT BLANK (DUPE OF PTX-178)			Exhibit not provided

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 369		Sun's Annotated Comparison of Proposed Labeling vs. Reference Listed Drug Labeling		SUN-BOS0000034 -35; SUN-BOS0000078 - 119	F, H
PTX - 370		Sun's Certificate of Analysis, Bosutinib, Batch No. BS0021215		SUN-BOS0003709 - 17	F, H, DUP
PTX - 371		Sun's Certificate of Analysis, Bosutinib Tablets, 100 mg, Batch No. GKR0157		SUN-BOS0000760 -65	F, H
PTX - 372		Sun's Certificate of Analysis, Bosutinib Tablets, 500 mg, Batch No. GKR0157		SUN-BOS0000766 -71	F, H
PTX - 373		Sun's Certificate of Analysis, Croscarmellose Sodium NF (AC-DI-SOL), Batch No. T1152C		SUN-BOS0001126 - 33	F, H
PTX - 374		Sun's Errata 2 to Scale Up Report Bosutinib Tablets 100 mg/500 mg		SUN-BOS0000649 -81	F, H
PTX - 375		Sun's Exhibit Batch Record, Bosutinib Tablets 100 mg, Batch No. GKR0160		SUN-BOS0000772 - 813	F, H, DUP
PTX - 376		Sun's Exhibit Batch Report, Bosutinib Tablets 100 mg and 500 mg, Batch Nos. GKR0157, GKR0158, GKR0159		SUN-BOS0000728 - 59	F, H
PTX - 377		Sun's Exhibit Batch Manufacturing Record, Bosutinib Tablets 100 mg and 500 MG, Batch No. GKR0157		SUN-BOS0002144 - 202	F, H

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 378		Sun's In Process - Analytical Test Procedure, Bosutinib Tablets, 100 mg		SUN-BOS0000696- 710	F, H
PTX - 379		Sun's In Process - Analytical Test Procedure, Bosutinib Tablets, 500 mg		SUN-BOS0000713- SUN-BOS0000727	F, H, DUP
PTX - 380		Sun's In Process - Specification Report, Bosutinib Tablets, 100 mg		SUN-BOS0000694 -95	F, H, DUP
PTX - 381		Sun's In Process - Specification Report, Bosutinib Tablets, 500 mg		SUN-BOS0000711 -12	F, H
PTX - 382		Sun's Master Batch Manufacturing Record, Bosutinib Tablets 100 mg and 500 mg		SUN-BOS0000814 - 944	F, H
PTX - 383		Sun's Master Batch Packing Record, Bosutinib Tablets 100 mg		SUN-BOS0000945 - 1064	F, H
PTX - 384		Sun's November 14, 2016 ANDA Notice Letter	11/14/2016		F, H
PTX - 385		Sun's Proposed Package Insert, Revised 09/2016	9/2016	SUN-BOS0000043 - 62	F, H, DUP
PTX - 386		Sun's Proposed Package Insert, Revised 02/2017	2/2017	SUN-BOS0024498 - 517; SUN-BOS0024524 - 543	F, H
PTX - 387		Sun's Proposed Patient Information		SUN-BOS0000063 - 65; SUN-BOS0024518 - 20; SUN-BOS0024521 - 23	F, H

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 388		Sun's Quantitative Formula for Opadry® II Complete Film Coating System 85F12390 Yellow Document		SUN-BOS0000489 - 90	F, H
PTX - 389		Sun's Reprocessing Statement, Bosutinib Tablets 100 mg and 500 mg		SUN-BOS0001065 - 66	F, H
PTX - 390	Mathur Ex. 47	Sun's Response to FDA Complete Response Letter Dated October 29, 2018	10/29/2018	SUN-BOS0089504 - 06	F, H
PTX - 391		Sun's Specification Report, Croscarmellose Sodium NF (AC-DI-SOL)		SUN-BOS0001140 - 42	F, H
PTX - 392		U.S. Pharmacopeia 27, Ch. 891, Thermal Analysis (27th rev. 2004)			F, H, U, R
PTX - 393		William Clegg, Crystal Structure Determination 1-21 (John Evans ed., 1998)			F, H, U, R, I
PTX - 394		Overlay Plot of XRPD pattern by Chyall			A, F, H, U, R
PTX - 395		Document highlighted by Chyall		SUN-BOS0024881 - 82	A, F, H, U, R, ILL
PTX - 396		Document highlighted by Chyall		SUN-BOS0024861	A, F, H, U, R, ILL
PTX - 397		Overlay Plot of XRPD pattern by Chyall		SUN-BOS0024879	A, F, H, U, R
PTX - 398		Overlay Plot of XRPD pattern by Chyall		SUN-BOS0024859	A, F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 399		Overlay Plot of XRPD pattern by Chyall		SUN-BOS0089455	A, F, H, U, R
PTX - 400		Overlay Plot of XRPD pattern by Chyall		SUN-BOS0089449	A, F, H, U, R
PTX - 401		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 402		INTENTIONALLY LEFT BLANK (DUPE OF PTX-299)			
PTX - 403		INTENTIONALLY LEFT BLANK (DUPE OF PTX-308)			Exhibit not provided
PTX - 404				PFE-BOS01588089	Exhibit not provided
PTX - 405		INTENTIONALLY LEFT BLANK (DUPE OF PTX-060)			Exhibit not provided
PTX - 406		INTENTIONALLY LEFT BLANK (DUPE OF PTX-013)			Exhibit not provided
PTX - 407		INTENTIONALLY LEFT BLANK (DUPE OF PTX-061)			Exhibit not provided
PTX - 408				PFE-BOS01598847	Exhibit not provided
PTX - 409				PFE-BOS01603413	Exhibit not provided

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 410				PFE-BOS01611622	Exhibit not provided
PTX - 411				PFE-BOS01611672	Exhibit not provided
PTX - 412				PFE-BOS01611682	Exhibit not provided
PTX - 413				PFE-BOS01632267	Exhibit not provided
PTX - 414				PFE-BOS01675512	Exhibit not provided
PTX - 415				PFE-BOS01775118	Exhibit not provided
PTX - 416				PFE-BOS01801604	Exhibit not provided
PTX - 417				PFE-BOS01801610	Exhibit not provided
PTX - 418				PFE-BOS01864462	Exhibit not provided
PTX - 419				PFE-BOS01864799	Exhibit not provided
PTX - 420				PFE-BOS01865310	Exhibit not

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
					provided
PTX - 421				PFE-BOS01868842	Exhibit not provided
PTX - 422				PFE-BOS02537413	Exhibit not provided
PTX - 423				PFE-BOS02541056	Exhibit not provided
PTX - 424				PFE-BOS02571580	Exhibit not provided
PTX - 425				PFE-BOS02572438	Exhibit not provided
PTX - 426		INTENTIONALLY LEFT BLANK (DUPE OF PTX-111)			Exhibit not provided
PTX - 427				PFE-BOS02576024	Exhibit not provided
PTX - 428				PFE-BOS02576236	F, H, U, R
PTX - 429				PFE-BOS02592019	Exhibit not provided
PTX - 430				PFE-BOS02597660	Exhibit not provided

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 431				PFE-BOS02612947	Exhibit not provided
PTX - 432		148 patent file history certificate		PFZFH0000001	I
PTX - 433				SUN-BOS0011862	Exhibit not provided
PTX - 434		INTENTIONALLY LEFT BLANK (DUPES OF PTX-016; PTX-311; PTX-432)			Exhibit not provided
PTX - 435		INTENTIONALLY LEFT BLANK (DUPES OF PTX-083; PTX-312; PTX-313)			Exhibit not provided
PTX - 436		INTENTIONALLY LEFT BLANK (DUPES OF PTX-150; PTX-314; PTX-315)			Exhibit not provided
PTX - 437		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 438		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 439		INTENTIONALLY LEFT BLANK			Exhibit not provided

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 440		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 441		Craig W Lindsley - CV			F, R
PTX - 442		INTENTIONALLY LEFT BLANK (DUPE OF PTX-150)			Exhibit not provided
PTX - 443		INTENTIONALLY LEFT BLANK (DUPE OF PTX-083)			Exhibit not provided
PTX - 444		Berger, et al., Synthesis and Evaluation of 4-Anilino-6,7-dialkoxy-3-quinolinecarbonitriles as Inhibitors of Kinases of the Ras-MAPK Signaling Cascade, Bioorg. Med. Chem. Lett. 13:3031-3034 (2003)	4/8/2003		F, H
PTX - 445	Lindsley Ex. 16	Boschelli, et al., Dual Src/Abl Kinase Inhibitor Causes Regression of CML Xenografts in Nude Mice, Blood 100:786a (2002)	11/16/2002		F, H
PTX - 446	Lindsley Ex. 18; Murcko Ex. N	Danhauser-Riedl et al., Activation of Src Kinases p53/56lyn and p59hck by p210bcr/abl in Myeloid Cells, Cancer Research 56:3589 (1996)	8/1/1996	SUN-BOS0011995 - 2003	F, H
PTX - 447	Lindsley Ex. 22	Deininger, et al., The Molecular Biology of Chronic Myeloid Leukemia, Blood	11/15/2000		F, H

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		96(10):3343-3356 (2000)			
PTX - 448		Donato, et al., Use of c-Src Inhibitors Alone or in Combination with STI571 for the Treatment of Leukemia, WO 03/013540	2/20/2003	SUN-BOS0012021 - 45	F, H, DUP
PTX - 449		International Application No. PCT/EP02/08941	1/17/2003		F, H
PTX - 450		U.S. Provisional Application No. 60/311,690	7/29/2002		F, H
PTX - 451	Murcko Ex. X	U.S. Patent Number 8,119,649	2/21/2012		F, H
PTX - 452	Murcko Ex. Y	U.S. Patent Number 8,268,837	9/18/2012		F, H
PTX - 453	Lindsley Ex. 23	Dorsey et al., The Pyrido[2,3-d]pyrimidine Derivative PD180970 Inhibits p210 Bcr-Abl Tyrosine Kinase and Induces Apoptosis of K562 Leukemic Cells, Cancer Research, 60, 2127-3131 (2000)	6/15/2000	SUN-BOS0012046 - 51	F, H, DUP
PTX - 454	Lindsley Ex. 21; Murcko Ex. H	Druker BJ & Lydon NB, Lessons Learned From The Development Of An Abl Tyrosine Kinase Inhibitor for Chronic Myelogenous Leukemia, The Journal of	1/2000		F, H

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		Clinical Investigation 105(1):3-7 (2000)			
PTX - 455	Lindsley Ex. 28; Murcko Ex. J	Druker, et al., Efficacy and Safety of a Specific Inhibitor of the Bcr-Abl Tyrosine Kinase in Chronic Myeloid Leukemia, New England J. of Med., 344, 1031-1037 (2001)	4/5/2001		F, H
PTX - 456	Lindsley Ex. 30; Murcko Ex. I	Druker, et al., Activity of a Specific Inhibitor of the Bcr-Abl Tyrosine Kinase in the Blast Crisis of Chronic Myeloid Leukemia and Acute Lymphoblastic Leukemia With the Philadelphia Chromosome, New England J. of Med., 344, 1038-1042 (2001)	4/5/2001		F, H
PTX - 457	Lindsley Ex. 31	Druker et al., Chronic Myelogenous Leukemia, Hematology 1:111-135 (2002)	2002		F, H, DUP
PTX - 458		Golas et al., SKI-606, a 4-Anilino-3-quinolinecarbonitrile Dual Inhibitor of Src and Abl Kinases, Is a Potent Antiproliferative Agent Against Chronic Myelogenous Leukemia Cells in Culture and Causes Regression of K562 Xenografts in Nude Mice, Cancer Res. 63:375 (2003)	1/15/2003	SUN-BOS0012168 - 75	F, H, DUP

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 459	Lindsley Ex. 24; Murcko Ex. L	Irby et al., Role of Src Expression and Activation in Human Cancer, Oncogene, 19, 5636-42 (2000)	2000	SUN-BOS0012211 - 27	F, H
PTX - 460	Lindsley Ex. 27	Kalidas et al., Chronic Myelogenous Leukemia, J. Am. Medical. Ass'n 286 (8):895-898	8/29/2001		F, H
PTX - 461	Lindsley Ex. 25	Lionberger et al., Transformation of Myeloid Leukemia Cells to Cytokine Independence by Bcr-Abl Is Suppressed by Kinase-defective Hck, J. Biol. Chem. 275:18581-18585 (2000)	6/16/2000		F, H
PTX - 462	Lindsley Ex. 36	Ma et al., Clinical trial designs for targeted agents, Hematol. Oncol. Clin. N. Am. 16:1287- 1305 (2002)	2002		F, H
PTX - 463	Lindsley Ex. 29	Mauro and Druker, STI571: Targeting BCR-ABL as Therapy for CML, The Oncologist 6:233 (2001) ("Mauro 2001")	5/21/2001	SUN-BOS0012227 -32	F, H, DUP
PTX - 464	Lindsley Ex. 20	Roginskaya, et al., Therapeutic Targeting of Src-Kinase Lyn in Myeloid Leukemic Cell Growth, Leukemia, 13, 855-861 (1999)	2/26/1999		F, H
PTX - 465		Stanglmaier et al., The Interaction of the Bcr-Abl Tyrosine Kinase with the Src Kinase Hck Is Mediated by Multiple	8/5/2002	SUN-BOS0012261 - 67	F, H

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		Binding Domains, Leukemia 17:283-289 (February 2003)			
PTX - 466		Tatton et al., The Src-selective Kinase Inhibitor PP1 Also Inhibits Kit and Bcr-Abl Tyrosine Kinases, J. Biol. Chem. 278(7):4847-4853	12/5/2002	SUN-BOS0012268 - 75	F, H
PTX - 467	Lindsley Ex. 34; Murcko Ex. T	Warmuth et al., Dual-Specific Src and Abl Kinase Inhibitors, PP1and CGP76030, Inhibit Growth and Survival of Cells Expressing Imatinib Mesylate-Resistant Bcr-Abl Kinases, Blood 101:664-672 (2003)	1/15/2003	SUN-BOS0012446 - 54	F, H
PTX - 468	Lindsley Ex. 38; Murcko Ex. LL	Wilson et al., Selective Pyrrolo-Pyrimidine Inhibitors Reveal a Necessary Role for Src Family Kinases in Bcr-Abl Signal Transduction and Oncogenesis, Oncogene. 21:8075-8088 (2002)	9/3/2002	SUN-BOS0012455 - 68	F, H
PTX - 469	Lindsley Ex. 26	Zhang, et al., Synthesis and Structure-Activity Relationships of 3-Cyano-4-(phenoxyanilino)quinolines as MEK (MAPKK) Inhibitors, Bioorg. Med. Chem. Lett. 10:2825-2828 (2000)	10/10/2000		F, H
PTX - 470		INTENTIONALLY LEFT BLANK			Exhibit not provided

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 471		Sun's ANDA		SUN-BOS0043648-55	
PTX - 472		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 473		Time Magazine Cover - http://content.time.com/time/covers/0,16641,20010528,00.html	5/28/2001		
PTX - 474		INTENTIONALLY LEFT BLANK			
PTX - 475		INTENTIONALLY LEFT BLANK			
PTX - 476		U.S. Patent Number 6,596,746			
PTX - 477		U.S. Patent Number 7,125,875			
PTX - 478		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 479		INTENTIONALLY LEFT BLANK			
PTX - 480		INTENTIONALLY LEFT BLANK			
PTX - 481		Kantarjian et al., Nilotinib in imatinib-resistant CML and Philadelphia chromosome-positive ALL, New Engl J Med 354(24):2542-51 (2006)			F, H

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 482		Norman, Drugs, Devices, and the FDA: Part 1: An Overview of Approval Processes for Drugs, JACC : Basic To Translational Science Vol. 1, No. 3, 170-179 (2016)			F, H
PTX - 483		SPRYCEL Prescribing Information, available at http://packageinserts.bms.com/pi/pisprycel.pdf			F, H
PTX - 484		Talpaz et al., Dasatinib in imatinib-resistant Philadelphia chromosome-positive leukemias, New Engl J. Med. 354(24):2531-41 (2006)	6/15/2006		F, H
PTX - 485		TASIGNA Prescribing Information, available at https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/tasigna.pdf			F, H
PTX - 486		Williams, et al., Insights into Src kinase functions: structural comparisons, Trends in Biochemical Sciences, 23(5):179-184 (1998)			F, H
PTX - 487		Wolff et al., Office of Laboratory Animal Welfare Frequently Asked Questions About the Public Health Service Policy on			F, H

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		Humane Care and Use of Laboratory Animals, 32 Lab Animal 33 (2003)			
PTX - 488		Zimmerman et al., Potent and Selective Inhibitors of the Abl-Kinase: Phenylaminopyrimidine (PAP) Derivatives, 7 Bioorganic & Med. Chemistry Letters 187 (1997)			F, H, U, R, DUP
PTX - 489		Study Evaluating SKI-606 (Bosutinib) In Philadelphia Chromosome Positive Leukemias - https://clinicaltrials.gov/ct2/show/NCT00261846?term=NCT00261846&rank=1			
PTX - 490		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 491		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 492		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 493		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 494		INTENTIONALLY LEFT BLANK			Exhibit not provided

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 495		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 496		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 497		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 498		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 499		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 500		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 501		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 502		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 503		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 504		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 505		INTENTIONALLY LEFT BLANK			Exhibit not

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
					provided
PTX - 506		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 507		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 508		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 509		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 510		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 511		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 512		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 513		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 514		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 515		Esfahani MK et al., Blastic Phase of Chronic Myelogenous Leukemia, 7 Cur. Treatment	2006		F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		Options in Oncology 189 (2006)			
PTX - 516		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 517		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 518		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 519		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 520		INTENTIONALLY LEFT BLANK			
PTX - 521		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 522		INTENTIONALLY LEFT BLANK (DUPE OF PTX-150)			Exhibit not provided
PTX - 523		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 524		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 525		INTENTIONALLY LEFT BLANK (DUPE OF PTX-016)			Exhibit not provided

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 526		INTENTIONALLY LEFT BLANK (DUPE OF PTX-083)			Exhibit not provided
PTX - 527		Mark Levis CV	12/1/2018		F, R
PTX - 528		Daud A. et al., Phase I Study of Bosutinib, a Src/Abl Tyrosine Kinase Inhibitor, Administered to Patients with Advanced Solid Tumors, 18 Clinical Cancer Res. 1092 (2012)	2012		F, H, U, R
PTX - 529		INTENTIONALLY LEFT BLANK (DUPE OF PTX-676)			
PTX - 530		Bosutinib 2011 Investigator's Brochure		PFE-BOS00302596 -770	F, H, U, R
PTX - 531		Druker et al., Effects of a Selective Inhibitor of the Abl Tyrosine Kinase on the Growth of Bcr-Abl Positive Cells, 2 Nature Med. 561 (1996)	1996		F, H, DUP
PTX - 532		Reigner & Karen Smith Blesch, Estimating the Starting Dose for Entry into Humans: Principles and Practice, 57 Eur. J. Clinical Pharmacology 835 (2002)			F, H, U, R
PTX - 533		Fuse E, et al., Prediction of the Maximal Tolerated Dose (MTD) and Therapeutic Effect of Anticancer Drugs in Humans: Integration of Pharmacokinetics with			F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		Pharmacodynamics and Toxicodynamics, 21 Cancer Treatment Reviews 133 (1995)			
PTX - 534		Boxenbaum H & Clifford DiLea, First-Time-in-Human Dose Selection: Allometric Thoughts and Perspectives, 35 J. Clinical Pharmacology. 957 (1995)	1995		F, H, U, R
PTX - 535		IND68268 Pre-IND Meeting Briefing Package February 2004		PFE-BOS01441751 - 823	F, H, U, R
PTX - 536		Konopka JB et al., An Alteration of the Human c-abl Protein in K562 Leukemia CellsUnmasks Associated Tyrosine Kinase Activity, 37 Cell 1035 (1984)			F, H, U, R
PTX - 537		Paxton JW, The Allometric Approach for Interspecies Scaling of Pharmacokinetics and Toxicity of Anti-Cancer Drugs, 22 Clinical & Experimental Pharmacology & Physiology 851 (1995)			F, H, U, R
PTX - 538		Cortes JE et al., Bosutinib Versus Imatinib for Newly Diagnosed Chronic Myeloid Leukemia: Results from the Randomized BFORE Trial, 36 J. Clinical Oncology 231 (2017)	2017		F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 539		Cortes JE et al., Safety and Efficacy of Bosutinib (SKI-606) in Chronic Phase Philadelphia Chromosome-Positive Chronic Myeloid Leukemia Patients with Resistance or Intolerance to Imatinib, 118 Blood 4567 (2011)	2011		F, H, U, R
PTX - 540		Roy L et al., Survival Advantage from Imatinib Compared with the Combination Interferon- α Plus Cytarabine in Chronic-Phase Chronic Myelogenous Leukemia: Historical Comparison Between Two Phase 3 Trials, 108 Blood 1478 (2006)			F, H, U, R
PTX - 541		Deininger MW et al., The Molecular Biology of Chronic Myeloid Leukemia, 96 Blood 3343 (2000)			F, H, DUP
PTX - 542		Takahashi N et al., Long-term Treatment with Bosutinib in a Phase 1/2 Study in Japanese Chronic Myeloid Leukemia Patients Resistant/Intolerant to Prior Tyrosine Kinase Inhibitor Treatment, 106 Int'l J. Hematology 398 (2017)			F, H, U, R
PTX - 543		National Cancer Institute Cancer Evaluation Program, Common Toxicity Criteria, Version 2.0 (1999)			F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 544		Shah NP et al., Intermittent Target Inhibition With Dasatinib 100 mg Once Daily Preserves Efficacy and Improves Tolerability in Imatinib-Resistant and -Intolerant Chronic- Phase Chronic Myeloid Leukemia, 26 J. Clinical Oncology 3204 (2008)			F, H, U, R
PTX - 545		von Bubnoff N et al., BCR-ABL Gene Mutations in Relation to Clinical Resistance of Philadelphia-Chromosome-Positive Leukaemia to STI571: A Prospective Study, 359 Lancet 487 (2002)			F, H, U, R
PTX - 546		Heisterkamp N et al., Structural Organization of the bcr Gene and Its Role in the Ph' Translocation, 315 Nature 758 (1985)			F, H, U, R
PTX - 547		INTENTIONALLY LEFT BLANK			F, H, U, R
PTX - 548		Amare PS et al., Flourescence in Situ Hybridization: A Highly Efficient Technique of Molecular Diagnosis and Prediction for Disease Course in Patients with Myeloid Leukemias, 131 Cancer Genetics & Cytogenetics 125, 126 (2001)			F, H, U, R
PTX - 549		Nowell PC, Discovery of the Philadelphia Chromosome: a Personal Perspective, 117			F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		J. Clinical Investigation 2033 (2007)			
PTX - 550		Coutre PI et al., In Vivo Eradication of Human BCR/ABL-Positive Leukemia Cells with an ABL Kinase Inhibitor, 91 J. Nat'l Cancer Inst., 163 (1999)			F, H, U, R
PTX - 551		Hehlmann Rudiger, et al., Management of CML-Blast Crisis, 29 Best Prac. & Res. Clinical Haematology 295 (2016)			F, H, U, R
PTX - 552		Hunter T & Bartholomew M. Sefton, Transforming Gene Product of Rous Sarcoma Virus Phosphorylates Tyrosine, 77 Biochemistry 1311 (1980)			F, H, U, R
PTX - 553		United States Dept. of Health & Human Services, Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0 (2017)	11/27/2017		F, H, U, R
PTX - 554		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 555		INTENTIONALLY LEFT BLANK			Exhibit not provided

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 556	Lindsley Ex. 32	Garcia-Manero et al., Current Therapy of Chronic Myelogenous Leukemia, Internal Medicine 41:254-264	4/1/2002		F, H
PTX - 557		Hantel et al., Imatinib is still recommended for frontline therapy for CML, Blood Advances Volume 2, Number 24: 3648-3652 (2018)			F, H
PTX - 558		Kalidas et al., Chronic Myelogenous Leukemia, J. Am. Medical. Ass'n 286 (8):895-898			F, H, DUP
PTX - 559		Norman, Drugs, Devices, and the FDA: Part 1: An Overview of Approval Processes for Drugs, JACC : Basic To Translational Science Vol. 1, No. 3, 170-179 (2016)			F, H, DUP
PTX - 560		Michael J Thirman - CV	2/13/2019		F, R
PTX - 561		Piotr H. Karpinski - CV			F, R
PTX - 562		INTENTIONALLY LEFT BLANK			
PTX - 563		INTENTIONALLY LEFT BLANK (DUPE OF PTX-083)			Exhibit not provided
PTX - 564		Grant DJW, Theory and origin of polymorphism, Polymorphism in			

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		Pharmaceutical Solids, 1-34 (Henry G. Brittain ed., Marcel Dekker, Inc. 1999)			
PTX - 565		INTENTIONALLY LEFT BLANK			
PTX - 566		INTENTIONALLY LEFT BLANK (DUPE OF PTX-812)			
PTX - 567		Vippagunta SR, Henry G. Brittain, & David J. W. Grant, Crystalline solids, Advanced Drug Delivery Reviews, 48:3-26 (May 16, 2001)	5/16/2001		
PTX - 568		INTENTIONALLY LEFT BLANK			
PTX - 569		Cruz-Cabeza AJ, Susan M. Reutzel-Edens, & Joel Bernstein, Facts and fictions about polymorphism, Chem. Soc. Rev., 44, 8619-8635 (2015)	2015		
PTX - 570		Stahly GP, Diversity in Single- and Multiple-Component Crystals. The Search for and Prevalence of Polymorphs and Cocrystals, Crystal Growth & Design, 7, 6, 1007–1026, SCSi (2007)		Alembic_Wyeth0329569 - 88	
PTX - 571		Karpinski PH, Polymorphism of Active Pharmaceutical Ingredients, Chemical Engineering & Technology, 29(2) 233-237			

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		(2006)			
PTX - 572		Nangia A & Desiraju GR, Pseudopolymorphism: occurrences of hydrogen bonding organic solvents in molecular crystals, Chemical Communications, 7, 605-606 (1999)		Alembic_Wyeth0329594 - 95	
PTX - 573		INTENTIONALLY LEFT BLANK			
PTX - 574		INTENTIONALLY LEFT BLANK			
PTX - 575		INTENTIONALLY LEFT BLANK			
PTX - 576		INTENTIONALLY LEFT BLANK			
PTX - 577		INTENTIONALLY LEFT BLANK			
PTX - 578		Sestak J, Thermophysical Properties of Solids – Their Measurements and Theoretical Thermal Analysis, Comprehensive Analytical Chemistry, Vol. XII, Thermal Analysis Part D, (Elsevier Science Publishing, 1984)		Alembic_Wyeth0329629 - 51	
PTX - 579		INTENTIONALLY LEFT BLANK			

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 580		INTENTIONALLY LEFT BLANK			
PTX - 581		INTENTIONALLY LEFT BLANK			
PTX - 582		Saganowska P. and Wesolowski M. (2017). DSC as a screening tool for rapid co-crystal detection in binary mixtures of benzodiazepines with co-formers. Journal of Thermal Analysis and Calorimetry		Alembic_Wyeth0329652 - 62	
PTX - 583		Haleblian J & McCrone W, Pharmaceutical Applications of Polymorphism. J. Pharm. Sci., 58: 911-929 (1969)		Alembic_Wyeth0329678 - 97	
PTX - 584		Gu CH, C., Victor G. Young, & David J.W. Grant, Polymorph Screening: Influence of Solvents on the Rate of Solvent-Mediated Polymorphic Transformation. J. Pharm. Sci., 90: 1878-1890 (2001)		Alembic_Wyeth0329698 - 710	
PTX - 585		INTENTIONALLY LEFT BLANK			
PTX - 586		Chemburkar SR, et al., Dealing with the Impact of Ritonavir Polymorphs on the Late Stages of Bulk Drug Process	2000	Alembic_Wyeth0329733 - 38	

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		Development, Org. Process Res. Dev., 4:413–417 (2000)			
PTX - 587		INTENTIONALLY LEFT BLANK			
PTX - 588		ICH Harmonised Tripartite Guideline, Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances Q6A, Public_Web_Site/ICH_Products/Guidelines/Quality/Q6A/Step4/Q6Astep4.pdf (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, October 6, 1999)			
PTX - 589		INTENTIONALLY LEFT BLANK (DUPE OF PTX-665)			
PTX - 590		Byrn S, Ralph Pfeiffer, Michael Ganey, Charles Hoiberg, & Guirag Poochikian, Pharmaceutical Solids: A Strategic Approach to Regulatory Considerations, Pharmaceutical Research, Vol. 12, No. 7 (1995)	1995		
PTX - 591		Guillory JK, Generation of Polymorphs, Hydrates, Solvates, and Amorphous			

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		Solids, Polymorphism in Pharmaceutical Solids, Brittain, H. G. (ed), New York 1999: M. Dekker			
PTX - 592		Desrosiers P., High-throughput screening techniques for preformulation: Salt selection and polymorph studies, Acta Crystallographica, A58(supplement), c9 (2002)		Alembic_Wyeth0331730	
PTX - 593		INTENTIONALLY LEFT BLANK (DUPE OF PTX-592)			
PTX - 594		Morissette SL et al., High-throughput crystallization: polymorphs, salts, co-crystals and solvates of pharmaceutical solids, Advanced Drug Delivery Reviews, 56(3):275-300 (2004)		Alembic_Wyeth0329784 - 809	
PTX - 595		INTENTIONALLY LEFT BLANK			
PTX - 596		Carlson ED et al., An integrated high throughput workflow for pre-formulations: Polymorph and salt selection studies, Drug Development, 10-15 (July/August 2003)	2003	Alembic_Wyeth0331734 - 39	
PTX - 597		INTENTIONALLY LEFT BLANK (DUPE OF PTX-004)			

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 598		INTENTIONALLY LEFT BLANK			
PTX - 599		INTENTIONALLY LEFT BLANK (DUPE OF PTX-676)			Exhibit not provided
PTX - 600		Brittain HG, Methods for the Characterization of Polymorphs and Solvates, in 95 Drugs and the Pharmaceutical Sciences, Polymorphism in Pharmaceutical Solids 227 (James Swarbrick ed., 1999)	1999		
PTX - 601		INTENTIONALLY LEFT BLANK			
PTX - 602		FDA Guidelines 1987			
PTX - 603		Alexander LE & Klug HP, Basic aspects of X-ray absorption in quantitative diffraction analysis of powder mixtures, Analytical Chemistry, 20, 886-889 (1948)		Alembic_Wyeth0331740 - 43	
PTX - 604		Klug HP & Alexander LE, X-ray Diffraction Procedures for Polycrystalline and Amorphous Materials (Wiley, 2nd ed 1974)		Alembic_Wyeth0330715 - 1706	

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 605		Chung FH, Quantitative interpretation of X-ray diffraction patterns of mixtures. II. Adiabatic principle of X-ray diffraction analysis of mixtures. J. Appl. Crystallogr, 7, 526-531 (1974)	1974	Alembic_Wyeth0330098 - 103	
PTX - 606		Hubbard CR, Evans EH, & SmithK , The reference intensity ratio, I/Ic, for computer simulated powder patterns, J. Appl. Crystallogr. 9, 169-174 (1976)		Alembic_Wyeth0330104 - 109	
PTX - 607		Chung FH, Quantitative interpretation of X-ray diffraction patterns. I. Matrixflushing method of quantitative multicomponent analysis, Jour. of Applied Crystallography, v. 7, 519-525 (1974)	1974	Alembic_Wyeth0330110 - 16	
PTX - 608		INTENTIONALLY LEFT BLANK			
PTX - 609		Hillier S., Accurate quantitative analysis of clay and other minerals in sandstones by XRD: comparison of a Rietveld and a reference intensity ratio (RIR) method and the importance of sample preparation, Clay Miner. 35, 291-302 (2000)		Alembic_Wyeth0331748 - 59	
PTX - 610		Rietveld H.M. , Line profiles of neutron powder-diffraction peaks for structure refinement. Acta Crystallographica, n.22,		Alembic_Wyeth0330117 - 18	

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		1151-1152 (1967)			
PTX - 611		Rietveld H.M. , A profile refinement method for nuclear and magnetic structures. Journal of Applied Crystallographic, v.2, 65-71, (1969)		Alembic_Wyeth0330119 - 25	
PTX - 612		Hill R.J. & Howard CJ, Journal of Applied Crystallography, 20: 467-74 (1987)		Alembic_Wyeth0330126 - 33	
PTX - 613		Young RA, Introduction to the Rietveld method - The Rietveld Method, 1-39 (Oxford University Press - IUCr Book Series, 1993)		Alembic_Wyeth0330134 - 443	
PTX - 614		Raven MD & Peter G. , Outcomes of 12 Years of the Reynolds Cup Quantitative Mineral Analysis Round Robin. Clays and Clay Minerals, 65(2): 122-134 (2017)		Alembic_Wyeth0330444 - 56	
PTX - 615		INTENTIONALLY LEFT BLANK (DUPE OF PTX-841)			
PTX - 616		Atici E.B., Karlıga B. (2015) Quantitative determination of two polymorphic forms of imatinib mesylate in a drug substance and tablet formulation by X-ray powder diffraction, differential scanning calorimetry and attenuated total reflectance Fourier transform infrared spectroscopy. J.		Alembic_Wyeth0330489 - 99	

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		Pharm. and Biomed. Analysis, 114, 330-340			
PTX - 617		Campbell Roberts S N , Williams A C , Grimsey I M , Booth S W (2002) Quantitative analysis of mannitol polymorphs. X-ray powder diffractometry - exploring preferred orientation effects. J. Pharm. and Biomed. Analysis, 28, 1149-1159	2002	Alembic_Wyeth0330500 - 11	
PTX - 618		Kuncham S, Shetea G and Arvind Kumar Bansal (2014) Quantification of clarithromycin polymorphs in presence of tablet excipients. J. Excipients and Food Chem. 5 (1) 65-78		Alembic_Wyeth0330512 - 25	
PTX - 619		Német Z, Sajó I, Demeter A. (2010) Rietveld refinement in the routine quantitative analysis of famotidine polymorphs. J. Pharm. and Biomed. Analysis, 51, 572-576		Alembic_Wyeth0330526 - 30	
PTX - 620		Dong W, Gilmore C, Barr G, DallmanC, Feeder N, Terry S. (2008). A quick method for the quantitative analysis of mixtures. 1. Powder X-Ray diffraction J Pharm Sci.		Alembic_Wyeth0330531 - 48	

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		97(6):2260-2276			
PTX - 621		Silva R P, M F S Ambrósio, E K Epprecht, R R Avillez, C A Achete , A Kuznetsov, L C Visentin (2016) Validation of the method of quantitative phase analysis by X-ray diffraction in API: case of Tibolone J. Phys.: Conf. Ser. 733 012030		Alembic_Wyeth0330549 - 54	
PTX - 622		Pecharsky et al., Fundamentals of Powder Diffraction and Structural Characterization of Materials, 356 (2003)		Alembic_Wyeth0330555 - 86	
PTX - 623		INTENTIONALLY LEFT BLANK			
PTX - 624		INTENTIONALLY LEFT BLANK (DUPE OF PTX-850)			
PTX - 625		INTENTIONALLY LEFT BLANK (DUPE OF PTX-851)			
PTX - 626		INTENTIONALLY LEFT BLANK			

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 627		Görbitz, C. H. & H.P. Hersleth, Acta Cryst., B56, 526–534, at 527 (2000)		Alembic_Wyeth0331760 - 68	
PTX - 628		INTENTIONALLY LEFT BLANK (DUPE OF PTX-146)			
PTX - 629		Infantes L, Chisholm J, Motherwell S., Extended motifs from water and chemical functional groups in organic molecular crystals, Cryst Eng Comm 5 (2003) 480–486			
PTX - 630		Eszter Tieger, “Investigation of the pharmaceutical applicability of solvates: screening, characterization, crystallization” PhD Thesis 2017, Budapest University of Technology and Economics, Faculty of Chemical Technology and Biotechnology, https://repozitorium.omikk.bme.hu/bitstream/handle/10890/5428/ertekezes.pdf?			

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 631		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 632		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 633		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 634		Davey R.J. & Garside J., From molecules to crystallizers, Oxford University Press, at 1-5, 36 - 43 (2000)	2000		F, H, ILL
PTX - 635		Franklin WMS & Macnutt B, Mechanics and Heat: a text book for colleges and technical schools, The Macmillan Company, 1910.			F, H, ILL
PTX - 636		Oka S. et al., H. Staurosporine, a Potent Platelet Aggregation Inhibitor from a Streptomyces Species. Agric. Biol. Chem., 50:2723-2727 (1986)			F, H
PTX - 637		Yu L., Amorphous pharmaceutical solids: preparation, characterization and stabilization, Adv Drug Deliver Rev. 48:27-42 at 31 (2001)	12/21/2000		F, H

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 638		INTENTIONALLY LEFT BLANK (DUPE OF PTX-150)			Exhibit not provided
PTX - 639		Optimization of 4-Phenylamino-3-quinolinecarbonitriles as Potent Inhibitors of Src Kinase Activity	10/17/2001		F, H, DUP
PTX - 640		CV of Bernhardt L. Trout			F, H, U, R
PTX - 641		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 642		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 643		Trout Material Considered			F, H, U, R
PTX - 644		Fundamentals of Medicinal Chemistry			F, H, U, R, I
PTX - 645		Handbook of Pharmaceutical Analysis			F, H, U, R, I
PTX - 646		Textbook of Drug Design and Discovery 3rd Edition			F, H, U, R, I
PTX - 647		Remington: The Science and Practice of Pharmacy Vol I; Chapter 38.			F, H, U, R, I
PTX - 648		Remington: The Science and Practice of Pharmacy Vol I; Chapter 10.			F, H, U, R, I
PTX - 649		Remington: The Science and Practice of Pharmacy Vol I; Chapter 36			F, H, U, R, I

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 650		Guideline for Industry Impurities in New Drug Substances			F, H, U, R
PTX - 651		The United States Pharmacopeia the National Formulary			F, H, U, R, I
PTX - 652		Handbook of Pharmaceutical Excipients 3rd Edition: Preface	1/1/2002		F, H, U, R, I
PTX - 653		Handbook of Pharmaceutical Excipients 3rd Edition: USP 1078	1/1/2002		F, H, U, R, I
PTX - 654		Handbook of Pharmaceutical Excipients 3rd Edition: Preface	1/1/2002		F, H, U, R, I
PTX - 655		Handbook of Pharmaceutical Excipients 3rd Edition: USP Polysorbate 80	1/1/2002		F, H, U, R, I
PTX - 656		Frequently Asked Questions About the Public Health Service Policy on Humane Care and Use of Laboratory Animals			F, H
PTX - 657		Product for Life Science Research: Sigma Catalog Tween 80			F, H, U, R, I ILL
PTX - 658		Product for Life Science Research: Sigma Catalog General Information			F, H, U, R, I
PTX - 659		Millipore Sima Tween 80			A, F, H, U, R
PTX - 660		Product for Life Science Research: Sigma			F, H, U, R, I,

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		Catalog Dextrose			ILL
PTX - 661		Pharmaceutical Grade Dextrose (Anhydrous & Monohydrate) At Best			A, F, H, U, R
PTX - 662		The United States Pharmacopeia the National Formulary: USP Water	1/1/2002		F, H, U, R, I
PTX - 663		Remington: The Science and Practice of Pharmacy Vol I; Chapter 41			F, H, U, R, I
PTX - 664		Remington: The Science and Practice of Pharmacy Vol I; Chapter 39			F, H, U, R, I
PTX - 665		Federal Register, Vol. 65, No. 251, 83041-83063 (December 29, 2000)	12/29/2000		F, H, U, R, I
PTX - 666		Guidance or Industry INDs for Phase 2 nd Phase 3 Studies			F, H, U, R
PTX - 667		Federal Register Vol. 62, No. 247	12/24/1997		F, H, U, R, I
PTX - 668		Handbook of Pharmaceutical Excipients 3rd Edition: Dextrose			F, H, U, R, I
PTX - 669		Handbook of Pharmaceutical Excipients 3rd Edition: Tween			F, H, U, R, I
PTX - 670		Development and optimization of industrial			F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		scale chromatography for use in manufacturing			
PTX - 671		Overhead Projector Demonstrations: A Simple Demonstration of the Effect of Impurities on Melting Pot	3/1/1995		F, H, U, R
PTX - 672		Remington: The Science and Practice of Pharmacy Vol I; Chapter 33			F, H, U, R
PTX - 673		Remington: The Science and Practice of Pharmacy Vol I; Chapter 17			F, H, U, R
PTX - 674		Remington: The Science and Practice of Pharmacy Vol I; Chapter 18			F, H, U, R
PTX - 675		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 676		Latest Version (August 2019) of the Label Bosulif			F, H, U, R
PTX - 677		INTENTIONALLY LEFT BLANK (DUPE OF PTX-128)			Exhibit not provided
PTX - 678		INTENTIONALLY LEFT BLANK (DUPE OF PTX-131)			Exhibit not provided
PTX - 679		INTENTIONALLY LEFT BLANK (DUPE OF PTX-126)			Exhibit not provided

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 680		INTENTIONALLY LEFT BLANK (DUPE OF PTX-130)			Exhibit not provided
PTX - 681		INTENTIONALLY LEFT BLANK (DUPE OF PTX-128)			Exhibit not provided
PTX - 682		INTENTIONALLY LEFT BLANK (DUPE OF PTX-129)			Exhibit not provided
PTX - 683		Deed of Conversion and Amendment to Articles of Association of Pfizer PFE Ireland Pharmaceuticals Holding 1 Cooperatief U.A.	12/30/2017	PFE-BOS02787326 - 43	F, H, U, R
PTX - 684		INTENTIONALLY LEFT BLANK (DUPE OF PTX-130)			Exhibit not provided
PTX - 685		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 686		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 687		INTENTIONALLY LEFT BLANK (DUPE OF PTX-016)			Exhibit not provided
PTX - 688		INTENTIONALLY LEFT BLANK (DUPE OF PTX-150)			Exhibit not provided
PTX - 689		Curriculum Vitae Neil Pravin Shah			F, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 690		Clinical Resistance to STI-571 Cancer Therapy Caused by BCR-ABL Gene Mutation or Amplification	8/3/2001		F, H, U, R
PTX - 691		Multiple BCR-ABL kinase domain mutations confer polyclonal D670resistance to the tyrosine kinase D682inhibitor imatinib (STI571) in chronic phase and blast crisis chronic myeloid leukemia (August 2002)			F, H, U, R
PTX - 692		Overriding Imatinib Resistance with a Novel ABL Kinase Inhibitor	7/16/2004		F, H, U, R
PTX - 693		Dasatinib in Imatinib-Resistant Philadelphia Chromosome-Positive Leukemias	6/15/2006		F, H, DUP
PTX - 694		Intermittent Target Inhibition With Dasatinib 100 mg Once Daily Preserves Efficacy and Improves Tolerability in Imatinib-Resistant and -Intolerant Chronic-Phase Chronic Myeloid Leukemia (2008)			F, H, U, R, DUP
PTX - 695		Dasatinib versus Imatinib in Newly Diagnosed Chronic-Phase Chronic Myeloid Leukemia			F, H, U, R
PTX - 696		Ponatinib in Refractory Philadelphia Chromosome-Positive	11/29/2012		F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		Leukemias			
PTX - 697		A Phase 2 Trial of Ponatinib in Philadelphia Chromosome-Positive Leukemias	11/7/2013		F, H, U, R
PTX - 698		Long-term outcome with dasatinib after imatinib failure in chronic-phase chronic myeloid leukemia: follow-up of a phase 3 study	4/10/2014		F, H, U, R
PTX - 699		MEK-Dependent Negative Feedback Underlies BCR-ABL-Mediated Oncogene Addiction	12/20/2013		F, H, U, R
PTX - 700		Phase I evaluation of XL019, an oral, potent, and selective JAK2 inhibitor	12/1/2013		F, H, U, R
PTX - 701		Crenolanib is a selective type I pan-FLT3 inhibitor	4/8/2014		F, H, U, R
PTX - 702		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 703		Material Considered			F, H, U, R
PTX - 704		Discovery of the Philadelphia chromosome: a personal perspective (August 2007)			F, H, U, R, DUP
PTX - 705		Blastic Phase of Chronic			F, H, U, R,

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		Myelogenous Leukemia (2006)			DUP
PTX - 706		Management of CML-blast crisis (2016)			F, H, U, R, DUP
PTX - 707		CML – a short history of treatment since the mid-20th century (2019)			F, H, U, R
PTX - 708		Leukemia in Atomic Bomb Survivors (1954)			F, H, U, R
PTX - 709		A New Consistent Chromosomal Abnormality in Chronic Myelogenous Leukaemia identified by Quinacrine Fluorescence and Giemsa Staining	6/1/1973		F, H, U, R
PTX - 710		Chronic Myelogenous Leukemia (2001)	8/22/2001		F, H, U, R, DUP
PTX - 711		Abelson murine leukaemia virus protein is phosphorylated in vitro to form phosphotyrosine (1980)			F, H, U, R
PTX - 712		Abelson murine leukemia virus: Structural requirements for transforming gene function	5/13/1982		F, H, U, R
PTX - 713		Localization of the c-abl oncogene adjacent to a translocation break point in chronic myelocytic leukaemia	11/17/1983		F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 714		An Alteration of the Human c-abl Protein in K562 Leukemia Cells Unmasks Associated Tyrosine Kinase Activity (July 1984)			F, H, U, R
PTX - 715		Nature International Weekly Journal of Science Vol 315 No 6020 (13-19 June 1985) Experimental Melting of Peridotite	6/13/1985		F, H, U, R
PTX - 716		Nature International Weekly Journal of Science Vol 315 No 6022 (27 June - 3 July 1985) Alpine Folding and Ductility	6/27/1985		F, H, U, R, ILL
PTX - 717		American Association for the Advancement of Science Vol 247 No 4946 (2 March 1990)	3/2/1990		F, H, U, R
PTX - 718		Induction of Chronic Myelogenous Leukemia in Mice by the P210 bcr/abl Gene of the Philadelphia Chromosome	2/16/1990		F, H, U, R
PTX - 719		In Vivo Tyrosine Phosphorylations of the Abelson Virus Transforming Protein Are Absent in Its Normal Cellular Homolog	7/3/1982		F, H, U, R
PTX - 720		Bcr-Abl Efficiently Induces a Myeloproliferative Disease and Production of Excess Interleukin-3 and Granulocyte-Macrophage Colony-Stimulating Factor	11/15/1998		F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		in Mice: A Novel Model for Chronic Myelogenous Leukemia			
PTX - 721		The molecular biology of chronic myeloid leukemia	11/15/2000		F, H, DUP
PTX - 722		Functional Cooperation among Ras, STAT5, and Phosphatidylinositol 3-Kinase Is Required for Full Oncogenic Activities of BCR/ABL in K562 Cells	1/4/2002		F, H, U, R
PTX - 723		Dissecting the Molecular Mechanism of Chronic Myelogenous Leukemia Using Murine Models	2/12/2002		F, H, U, R
PTX - 724		A TRANSMISSIBLE AVIAN NEOPLASM. (SARCOMA OF THE COMMON FOWL.)	9/1/1910		F, H, U, R
PTX - 725		Detection and Enumeration of Transformation-Defective Strains of Avian Sarcoma Virus with Molecular Hybridization	9/27/1976		F, H, U, R
PTX - 726		Uninfected vertebrate cells contain a protein that is closely related to the product of the avian sarcomavirus transforming gene (src)	12/26/1978		F, H, U, R

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PTX - 727		The Nobel Prize in Physiology or Medicine 1989	10/9/1989		F, H, U, R
PTX - 728		Transforming gene product of Rous sarcoma virus phosphorylates tyrosine	12/3/1979		F, H, U, R
PTX - 729		Nature Genetics Vol 21 No 2 (February 1999): Activating SRC mutation in a subset of advanced human colon cancers			F, H, U, R
PTX - 730		Role of Src expression and activation in human cancer			F, H, DUP
PTX - 731		The protein tyrosine kinase family of the human genome (2002)			F, H, U, R
PTX - 732		Structural basis for selective inhibition of Src family kinases by PP1	6/25/1999		F, H, U, R, DUP
PTX - 733		Activation of Src Kinases p53/56lyn and p59hck by p210bcr/abl in Myeloid Cells	8/1/1996		F, H, DUP
PTX - 734		Transformation of Myeloid Leukemia Cells to Cytokine Independence by Bcr-Abl Is Suppressed by Kinase-defective Hck	4/14/2000		F, H, DUP
PTX - 735		Lessons learned from the development of an Abl tyrosine kinase inhibitor for			F, H, DUP

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		chronic myelogenous leukemia (January 2000)			
PTX - 736		Effects of a selective inhibitor of the Abl tyrosine kinase on the growth of Bcr-Abl positive cells	5/5/1996		F, H, DUP
PTX - 737		Chronic Myelogenous Leukemia (2002)			F, H, DUP
PTX - 738		Crystal Structures of the Kinase Domain of c-Abl in Complex with the Small Molecule Inhibitors PD173955 and Imatinib (STI-571)	8/1/2002		F, H, U, R, DUP
PTX - 739		BCR-ABL gene mutations in relation to clinical resistance of Philadelphia-chromosome-positive leukaemia to STI571: a prospective study	2/2/2002		F, H, U, R, DUP
PTX - 740		Discovery of a Novel, Potent, and Src Family-selective Tyrosine Kinase Inhibitor	1/12/1996		F, H, U, R, DUP
PTX - 741		The Pyrido[2,3-d]pyrimidine Derivative PD180970 Inhibits p210Bcr-Abl Tyrosine Kinase and Induces Apoptosis of K562 Leukemic Cells	6/15/2000		F, H, DUP

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 742		Characterization of Potent Inhibitors of the Bcr-Abl and the c-Kit Receptor Tyrosine Kinases	8/1/2002		F, H, DUP
PTX - 743		Dual-specific Src and Abl kinase inhibitors, PP1 and CGP76030, inhibit growth and survival of cells expressing imatinib mesylate—resistant Bcr-Abl kinases	1/15/2003		F, H, DUP
PTX - 744		In Vitro Pharmacological Characterization of PD 166285, a New Nanomolar Potent and Broadly Active Protein Tyrosine Kinase Inhibitor	8/4/1997		F, H, U, R
PTX - 745		Therapeutic targeting of Src-kinase Lyn in myeloid leukemic cell growth (1999)	2/26/1999		F, H, DUP
PTX - 746		Inhibition of Src Kinases by a Selective Tyrosine Kinase Inhibitor Causes Mitotic Arrest	12/15/1999		F, H, U, R, DUP
PTX - 747		Biochemical and Cellular Effects of c-Src Kinase-Selective Pyrido[2,3-d]pyrimidine Tyrosine Kinase Inhibitors (2000)	3/1/2000		F, H, U, R
PTX - 748		Molecular Characterization and Sensitivity of STI-571 (Imatinib Mesylate, Gleevec)-resistant, Bcr-Abl-positive, Human Acute	10/15/2002		F, H, DUP

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		Leukemia Cells to SRC Kinase Inhibitor PD180970 and 17-Allylamino-17-demethoxygeldanamycin			
PTX - 749		Geldanamycin and Its Analogue 17-Allylamino-17-demethoxygeldanamycin Lowers Bcr-Abl Levels and Induces Apoptosis and Differentiation of Bcr-Abl-positive Human Leukemic Blasts	3/1/2001		F, H, U, R
PTX - 750		Optimization of 4-Phenylamino-3-quinolinecarbonitriles as Potent Inhibitors of Src Kinase Activity	5/21/2001		F, H, DUP
PTX - 751		blood Journal of the American Society of Hematology Vol 100 No 11	11/16/2002		F, H, U, R
PTX - 752		CML Biology and Therapy Abstract # 1431 - 1434			F, H, U, R
PTX - 753		SKI-606, a 4-Anilino-3-quinolinecarbonitrile Dual Inhibitor of Src and abl Kinases, Is a Potent Antiproliferative Agent against Chronic Myelogenous Leukemia Cells in Culture and Causes Regression of K562 Xenografts in Nude Mice			F, H, DUP
PTX - 754		Selective pyrrolo-pyrimidine inhibitors			F, H, DUP

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		reveal a necessary role for Src family kinases in Bcr — Abl signal transduction and onco genesis (2002)			
PTX - 755		Synthesis and Structure-Activity Relationships of 3-Cyano-4-(phenoxyanilino)quinolines as MEK (MAPKK) Inhibitors	10/10/2000		F, H, DUP
PTX - 756		EFFICACY AND SAFETY OF A SPECIFIC INHIBITOR OF THE BCR-ABL TYROSINE KINASE IN CHRONIC MYELOID LEUKEMIA	4/5/2001		F, H, DUP
PTX - 757		ACTIVITY OF A SPECIFIC INHIBITOR OF THE BCR-ABL TYROSINE KINASE IN THE BLAST CRISIS OF CHRONIC MYELOID LEUKEMIA AND ACUTE LYMPHOBLASTIC LEUKEMIA WITH THE PHILADELPHIA CHROMOSOME	4/5/2001		F, H, DUP
PTX - 758		TI571: Targeting BCR-ABL as Therapy for CML (2001)	5/11/2001		F, H, DUP
PTX - 759		Current Therapy of Chronic Myelogenous Leukemia (April 2002)			F, H, DUP
PTX - 760		Clinical trial designs for targeted agents (2002)			F, H, DUP

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 761		INTENTIONALLY LEFT BLANK (DUPE OF PTX-165)			Exhibit not provided
PTX - 762		Use of c-Src inhibitors alone or in combination with STI571 for the treatment of leukaemia			F, H, DUP
PTX - 763		Comparison of effects of the tyrosine kinase inhibitors AG957, AG490, and STI571 on BCR-ABL-expressing cells, demonstrating synergy between AG490 and STI571 (2001)	4/1/2001		F, H, U, R
PTX - 764		The interaction of the Bcr-Abl tyrosine kinase with the Src kinase Hck is mediated by multiple binding domains	8/5/2002		F, H, DUP
PTX - 765		The Src-selective Kinase Inhibitor PP1 Also Inhibits Kit and Bcr-Abl Tyrosine Kinases	12/9/2002		F, H, DUP
PTX - 766		Synthesis and Evaluation of 4-Anilino-6, 7-dialkoxy-3-quinolinecarbonitriles as Inhibitors of Kinases of the Ras-MAPK Signaling Cascade	4/8/2003		F, H, DUP
PTX - 767		Structural and Signaling Requirements for BCR-ABL-Mediated Transformation and Inhibition of Apoptosis	6/29/1995		F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 768		Selective induction of apoptosis in Philadelphia chromosome-positive chronic myelogenous leukemia cells by an inhibitor of BCR - ABL tyrosine kinase, CGP 57148 (1998)			F, H, U, R
PTX - 769		INTENTIONALLY LEFT BLANK (DUPE OF PTX-529)			Exhibit not provided
PTX - 770		Safety and efficacy of bosutinib (SKI-606) in chronic phase Philadelphia chromosome-positive chronic myeloid leukemia patients with resistance or intolerance to imatinib	10/27/2011		F, H, U, R, DUP
PTX - 771		A Novel Inhibitor of the Tyrosine Kinase Src Suppresses Phosphorylation of Its Major Cellular Substrates and Reduces Bone Resorption In Vitro and in Rodent Models In Vivo (1999)			F, H, U, R
PTX - 772		Provisional Application for Patent Cover Sheet	8/10/2001		F, H, U, R
PTX - 773		INTENTIONALLY LEFT BLANK (DUPE OF PTX-016)			Exhibit not provided

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 774		INTENTIONALLY LEFT BLANK (DUPE OF PTX-150)			Exhibit not provided
PTX - 775		Neil Shah - CV	2/21/2019		F, R, DUP
PTX - 776		Gorre M, et al. , Clinical Resistance to STI-571 Cancer Therapy Caused by BCR-ABL Gene Mutation or Amplification, 293 Science 876 (2001)	8/3/2001		F, H, U, R, DUP
PTX - 777		Shah NP, Nicoll JM, Nagar B, Gorre ME, Paquette RL, Kuriyan J, Sawyers CL. Multiple BCR-ABL kinase domain mutations confer polyclonal resistance to the tyrosine kinase inhibitor imatinib (STI571) in chronic phase and blast crisis chronic myeloid leukemia. Cancer Cell. 2002 Aug;2(2):117-25	8/2/2002		F, H, U, R, DUP
PTX - 778		Shah NP, Tran C, Lee FY, Chen P, Norris D, Sawyers CL. Overriding imatinib resistance with a novel ABL kinase inhibitor. Science. 2004 Jul 16;305(5682):399-401	7/16/2004		F, H, U, R, DUP
PTX - 779		Dasatinib in Imatinib-Resistant Philadelphia Chromosome-Positive Leukemias Vol 354 No 24 (Pg 2531 - 2541)	6/15/2006		F, H, DUP

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 780		Shah NP, Kantarjian HM, Kim DW, Réa D, Dorlhiac-Llacer PE, Milone JH, Vela-Ojeda J, Silver RT, Khoury HJ, Charbonnier A, Khoroshko N, Paquette RL, Deininger M, Collins RH, Otero I, Hughes T, Bleickardt E, Strauss L, Francis S, Hochhaus A. Intermittent target inhibition with dasatinib 100 mg once daily preserves efficacy and improves tolerability in imatinib-resistant and -intolerant chronic-phase chronic myeloid leukemia. J Clin Oncol. 2008 Jul 1;26(19):3204-12	7/1/2008		F, H, U, R, DUP
PTX - 781		Kantarjian H, Shah NP, Hochhaus A, Cortes J, Shah S, Ayala M, Moiraghi B, Shen Z, Mayer J, Pasquini R, Nakamae H, Huguet F, Boqué C, Chuah C, Bleickardt E, Bradley-Garelik MB, Zhu C, Szatrowski T, Shapiro D, Baccarani M. Dasatinib versus imatinib in newly diagnosed chronic-phase chronic myeloid leukemia. N Engl J Med. 2010 Jun 17;362(24):2260-70	6/17/2010		F, H, U, R, DUP
PTX - 782		Cortes JE, Kantarjian H, Shah NP, Bixby D, Mauro MJ, Flinn I, O'Hare T, Hu S, Narasimhan NI, Rivera VM, Clackson T,	11/29/2012		F, H, U, R, DUP

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		Turner CD, Haluska FG, Druker BJ, Deininger MW, Talpaz M. Ponatinib in refractory Philadelphia chromosome-positive leukemias. N Engl J Med. 2012 Nov 29;367(22):2075-88			
PTX - 783		Cortes JE, Kim DW, Pinilla-Ibarz J, le Coutre P, Paquette R, Chuah C, Nicolini FE, Apperley JF, Khoury HJ, Talpaz M, DiPersio J, DeAngelo DJ, Abruzzese E, Rea D, Baccarani M, Müller MC, Gambacorti-Passerini C, Wong S, Lustgarten S, Rivera VM, Clackson T, Turner CD, Haluska FG, Guilhot F, Deininger MW, Hochhaus A, Hughes T, Goldman JM, Shah NP, Kantarjian H. A phase 2 trial of ponatinib in Philadelphia chromosome-positive leukemias. N Engl J Med. 2013 Nov 7;369(19):1783-96	11/7/2013		F, H, U, R, DUP
PTX - 784		Shah NP, Guilhot F, Cortes JE, Schiffer CA, le Coutre P, Brümmendorf TH, Kantarjian HM, Hochhaus A, Rousselot P, Mohamed H, Healey D, Cunningham M, Saglio G. Long-term outcome with dasatinib after imatinib failure in chronic-phase chronic myeloid leukemia: follow-up of a phase 3 study. Blood. 2014 Apr	4/10/2014		F, H, U, R, DUP

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		10;123(15):2317-24			
PTX - 785		Asmussen J, Lasater EA, Tajon C, Oses-Prieto J, Jun YW, Taylor BS, Burlingame A, Craik CS, Shah NP. MEK-dependent negative feedback underlies BCR-ABL-mediated oncogene addiction. Cancer Discov. 2014 Feb;4(2):200-15.	2/2014		F, H, U, R, DUP
PTX - 786		Verstovsek S, Tam CS, Wadleigh M, Sokol L, Smith CC, Bui LA, Song C, Clary DO, Olszynski P, Cortes J, Kantarjian H, Shah NP. Phase I evaluation of XL019, an oral, potent, and selective JAK2 inhibitor. Leuk Res. 2014 Mar;38(3):316-22	3/2014		F, H, U, R, DUP
PTX - 787		Smith CC, Lasater EA, Lin KC, Wang Q, McCreery MQ, Stewart WK, Damon LE, Perl AE, Jeschke GR, Sugita M, Carroll M, Kogan SC, Kuriyan J, Shah NP. Crenolanib is a selective type I pan-FLT3 inhibitor. Proc Natl Acad Sci U S A. 2014 Apr 8;111(14):5319-24	4/8/2014		F, H, U, R, DUP
PTX - 788		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 789		Materials Considered			F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 790		Peter. C. Nowell, Discovery of the Philadelphia Chromosome: a Personal Perspective, 117 J. Clin. Invest. 2033 (2007)			F, H, U, R, DUP
PTX - 791		INTENTIONALLY LEFT BLANK (DUPE OF PTX-536)			
PTX - 792		Nora Heisterkamp et al., Structural Organization of the bcr Gene and its Role in the Ph' Translocation, 315 Nature 758 (1985)	6/2/1985		F, H, U, R, DUP
PTX - 793		Merat Karbasian Esfahani, et al. Blastic Phase of Chronic Myelogenous Leukemia (2006)			F, H, U, R, DUP
PTX - 794		Rüdiger Hehlmann et al., Management of CML-Blast Crisis, 29 Best Prac. & Res. Clin. Haematology 295 (2016)			F, H, U, R, DUP
PTX - 795		Nikolas von Bubnoff, et al., Bcr-Abl Gene Mutations in Relation to Clinical Resistance of Philadelphia-Chromosome-Positive Leukaemia to STI571: a Prospective Study, 359 Lancet 487 (2002)			F, H, U, R, DUP
PTX - 796		INTENTIONALLY LEFT BLANK (DUPE OF PTX-529)			Exhibit not provided

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 797		INTENTIONALLY LEFT BLANK (DUPE OF PTX-182)			Exhibit not provided
PTX - 798		INTENTIONALLY LEFT BLANK (DUPE OF PTX-183)			Exhibit not provided
PTX - 799		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 800		INTENTIONALLY LEFT BLANK (DUPE OF PTX-243)			Exhibit not provided
PTX - 801		Gleevec Prescribing Information (pg 1-23)			F, H, U, R
PTX - 802		Brian J. Druker, et al. Efficacy and Safety of a Specific Inhibitor of the bcr-abl Tyrosine kinase in chronic myeloid Leukemia	4/5/2001		F, H, DUP
PTX - 803		Jorge Cortes, et al. Safety and efficacy of bosutinib (SKI-606) in chronic phase Philadelphia chromosome–positive chronic myeloid leukemia patients with resistance or intolerance to imatinib	10/27/2011		F, H, U, R, DUP
PTX - 804		Jorge Cortes, et al. Bosutinib Versus Imatinib in Newly Diagnosed Chronic-Phase Chronic Myeloid Leukemia: Results From the BELA Trial (2012)	10/1/2012		F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 805		B Hanfstein, et al. Early molecular and cytogenetic response is predictive for long-term progression-free and overall survival in chronic myeloid leukemia (CML)	4/24/2012		F, H, U, R
PTX - 806		Julieta Politi, et al. What Does a Deep Molecular Response Signify?	2/10/2014		F, H, U, R
PTX - 807		INTENTIONALLY LEFT BLANK (DUPE OF PTX-083)			Exhibit not provided
PTX - 808		CV of Leonard J. Chyall	4/21/2019		F, R, DUP
PTX - 809		Chyall Materials Considered (5/31/19 Validity Report)			F, H, U, R
PTX - 810		William Clegg, Crystal Structure Determination 1-21 (John Evans ed., 1998)			F, H, U, R, I, DUP
PTX - 811		John K. Haleblan, Characterization of Habits and Crystalline Modification of Solids and Their Pharmaceutical Applications (August 1975)			F, H, U, R, DUP
PTX - 812		Joel Bernstein, Polymorphism in Molecular Crystals (2002)			F, H, I
PTX - 813		The United States Pharmacopeia The National Formulary, USP 28 (2513- 2515)			F, H, U, R, I

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 814		Igor Ivanisevic, Uses of X-Ray Powder Diffraction In the Pharmaceutical Industry (2010)			F, H, U, R, DUP
PTX - 815		The United States Pharmacopeia The National Formulary, USP 25 (2033-2034)			F, H, U, R, I
PTX - 816		Royston M. Roberts et al. Modern Experimental Organic Chemistry, Chap 3			F, H, U, R, I
PTX - 817		The United States Pharmacopeia The National Formulary, USP 27 (2394-2396)			F, H, U, R, I
PTX - 818		Harry G. Brittain, Polymorphism in Pharmaceutical Solids		Alembic_Wyeth0329843 - 30071	
PTX - 819		Stephen Byrn, et al. Pharmaceutical Solids: A Strategic Approach to Regulatory Considerations (1995)		Alennbic_Wyeth0329774 - 83	
PTX - 820		Chong-Hui Gu et al. Polymorph Screening: Influence of Solvents on the Rate of Solvent-Mediated Polymorphic Transformation		Alennbic_Wyeth0329698 - 710	
PTX - 821		Diane H. Boschelli et al. Optimization of 4-Phenylamino-3-quinolinecarbonitriles as Potent Inhibitors of Src Kinase Activity (3965-3977)	10/17/2001	Alembic_Wyeth0329810 - 22	F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 822		Diane H. Boschelli et al. Optimization of 4-Phenylamino-3-quinolinecarbonitriles as Potent Inhibitors of Src Kinase Activity (3965-3977)	10/17/2001	Alembic_Wyeth0329810 - 22	
PTX - 823		Jennifer M. Golas et al. SKI-606, a 4-Anilino-3-quinolinecarbonitrile Dual Inhibitor of Src and Abl Kinases, Is a Potent Antiproliferative Agent against Chronic Myelogenous Leukemia Cells in Culture and Causes Regression of K562 Xenografts in Nude Mice		Alembic_Wyeth0329823 - 30	
PTX - 824		PROCESS FOR THE PREPARATION OF 7-SUBSTITUTED-3-QUINOLINE AND 3-QUINOL-4-OL CARBONITRILES	11/13/2003		F, H
PTX - 825		ICH Topic Q 6 A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances		SUN-BOS0012065 - 96	F, H, U, R
PTX - 826		Committee for Proprietary Medicinal Products (CPMP)	12/17/2003	SUN-BOS0012052 - 64	F, H, U, R
PTX - 827		SPECIFICATIONS: TEST PROCEDURES AND ACCEPTANCE CRITERIA FOR NEW DRUG SUBSTANCES AND NEW DRUG	10/6/1999	Alembic_Wyeth0329739 - 73	

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		PRODUCTS: CHEMICAL SUBSTANCES			
PTX - 828		Guideline for Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substances (February 1987)		Alembic_Wyeth0332030 - 77	F, H
PTX - 829		U.S. 7,417,148 B2	8/26/2008	Alembic_Wyeth0015924 - 33	F, H
PTX - 830		Guideline for Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substances (February 1987)		Alembic_Wyeth0332030 - 77	
PTX - 831		U.S. 7,417,148 B2	8/26/2008	Alembic_Wyeth0015924 - 33	F, H, U, R, I, DUP
PTX - 832		INTENTIONALLY LEFT BLANK (DUPE OF PTX-016)			
PTX - 833		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 834		Richard W. Ramette Chemical Equilibrium and Analysis Chapter 3			F, H, U, R, I
PTX - 835		John R. Taylor An Introduction to Error Analysis the Study of Uncertainties in Physical Measurements			F, H, U, R, I

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 836		Sampath S. Iyengar et al. Quantitative analyses of complex pharmaceutical mixtures by the Rietveld method	10/19/2000		F, H, U, R
PTX - 837		Mark D. Raven Outcomes of 12 Years of the Reynolds Cup Quantitative Mineral Analysis Round Robin		Alembic_Wyeth0330444 - 56	
PTX - 838		S. Hillier, Accurate quantitative analysis of clay and other minerals in sandstones by XRD: comparison of a Rietveld and a reference intensity ratio (RIR) method and the importance of sample preparation		Alembic_Wyeth0331748 - 59	F, H, U, R
PTX - 839		S. Hillier, Accurate quantitative analysis of clay and other minerals in sandstones by XRD: comparison of a Rietveld and a reference intensity ratio (RIR) method and the importance of sample preparation		Alembic_Wyeth0331748 - 59	
PTX - 840		Esen Bellur Atici et al. Quantitative determination of two polymorphic forms of imatinib mesylate in a drug substance and tablet formulation by X-ray powder diffraction, differential scanning calorimetry and attenuated total reflectance Fourier transform infrared spectroscopy	6/7/2014	Alembic_Wyeth0330489 - 99	

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 841		Jing-bo Qiu et al. Quantification of febuxostat polymorphs using powder X-ray diffraction technique (298-303)	1/5/2015		F, H, U, R
PTX - 842		Sarra N. Campbell et al. Quantitative analysis of manitol polymorphs. X-ray powder diffractometry-exploring preferred orientation effects		Alembic_Wyeth0330500 - 11	
PTX - 843		Swathi Kuncham et al. Quantification of clarithromycin polymorphs in presence of tablet excipients	3/2/2014	Alembic_Wyeth0330512 - 25	
PTX - 844		Zoltan Nemet et al. Rietveld refinement in the routine quantitative analysis of famotidine polymorphs		Alembic_Wyeth0330526 - 30	
PTX - 845		Wei Dong et al. A Quick Method for the Quantitative Analysis of Mixtures 2260 - 2276	7/2/2007	Alembic_Wyeth0330531 - 48	
PTX - 846		R P Silva et al. Validation of the method of quantitative phase analysis by X-ray diffraction in API: case of Tibolone		Alembic_Wyeth0330549 - 54	
PTX - 847		INTENTIONALLY LEFT BLANK (DUPE OF PTX-330)			
PTX - 848		A.G. De La Torre et al. Rietveld quantitative amorphous content analysis			F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		(2001)			
PTX - 849		Polymorphs of an active pharmaceutical ingredient/Patent	12/29/2011		F, H, U, R
PTX - 850		U.S. Patent 7,345,171 B2	3/18/2008		F, H, U, R
PTX - 851		U.S. Patent 7,977,357 B2	7/12/2011		F, H, U, R
PTX - 852		U.S. Patent 5,118,483	6/2/1992		F, H, U, R
PTX - 853		U.S. Patent 9,024,068 B2	5/5/2015		F, H, U, R
PTX - 854		U.S. Patent 9,718,846 B1	8/1/2017		F, H, U, R
PTX - 855		U.S. Patent 10,087,193 B2	10/2/2018		F, H, U, R
PTX - 856		International Publication Number WO 2015/149727 A1	1/8/2015		F, H, U, R
PTX - 857		INTENTIONALLY LEFT BLANK (DUPE OF PTX-330)			
PTX - 858		Vogel's Textbook of Practical Organic Chemistry Including Qualitative Organic Analysis			F, H, U, R, I

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 859		U.S. Patent Application Publication US 2005/0101780 A1	5/12/2005		F, H, U, R
PTX - 860		INTENTIONALLY LEFT BLANK (DUPE OF PTX-016)			Exhibit not provided
PTX - 861		INTENTIONALLY LEFT BLANK (DUPE OF PTX-150)			Exhibit not provided
PTX - 862		CV Mark A. Murcko	5/11/2019		F, R, DUP
PTX - 863		International Publication Nuo WO 03/013540 A1	2/20/2003		F, H, DUP
PTX - 864		Diane H. Boschelli et al. Optimization of 4-Phenylamino-3-quinolinecarbonitriles as Potent Inhibitors of Src Kinase Activity (3965-3977)	10/17/2001		F, H, DUP
PTX - 865		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 866		Murcko Materials Considered			F, H, U, R
PTX - 867		Brian J. Druker, et al. Lessons learned from the development of an Abl tyrosine kinase inhibitor for chronic myelogenous leukemia (January 2000)			F, H, DUP

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 868		Brian J. Druker, et al. ACTIVITY OF A SPECIFIC INHIBITOR OF THE BCR-ABL TYROSINE KINASE IN THE BLAST CRISIS OF CHRONIC MYELOID LEUKEMIA AND ACUTE LYMPHOBLASTIC LEUKEMIA WITH THE PHILADELPHIA CHROMOSOME	4/5/2001		F, H, DUP
PTX - 869		Brian J. Druker et al. EFFICACY AND SAFETY OF A SPECIFIC INHIBITOR OF THE BCR-ABL TYROSINE KINASE IN CHRONIC MYELOID LEUKEMIA	4/5/2001		F, H, DUP
PTX - 870		Mark M. Moasser et al., Inhibition of Src Kinases by a Selective Tyrosine Kinase Inhibitor Causes Mitotic Arrest, 6145 (1999)			F, H, U, R, DUP
PTX - 871		Rosalyn B Irby et al. Role of Src expression and activation in human cancer (2000) 5636-5642			F, H, DUP
PTX - 872		Yi Liu et al., Structural Basis for Selective Inhibition of Src Family Kinases by PP1	8/13/1999		F, H, U, R, DUP
PTX - 873		Susanne Danhauser-Riedl et al., Activation of Src Kinases p53/56lin and p59hck by p210bcr/abl in Myeloid Cells (1996)			F, H, DUP

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 874		Markus Warmuth et al., The Src Family Kinase Hck Interacts with Bcr-Abl by a Kinase-independent Mechanism and Phosphorylates the Grb2-binding Site of Bcr	9/24/1997		F, H, DUP
PTX - 875		Brian J. Druker et al. Chronic Myelogenous Leukemia (2000)			F, H, DUP
PTX - 876		Brian J. Druker et al., Effects of a selective inhibitor of the Abl tyrosine kinase on the growth of Bcr-Abl positive cells (May 1996)			F, H, DUP
PTX - 877		Jeffrey H. Hanket et al., Discovery of a Novel, Potent, and Src Family-selective Tyrosine Kinase Inhibitor Vol 271 No2 (695-701)	1/12/1996		F, H, U, R, DUP
PTX - 878		Jay F. Dorsey et al. The Pyrido[2,3-d]pyrimidine Derivative PD180970 Inhibits p210Bcr-Abl Tyrosine Kinase and Induces Apoptosis of K562 Leukemic Cells (2000)			F, H, DUP
PTX - 879		Markus Warmuth et al., Dual-specific Src and Abl kinase inhibitors, PP1 and CGP76030, inhibit growth and survival of cells expressing imatinib mesylate—resistant Bcr-Abl kinases	1/15/2003		F, H, DUP

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		(2003)			
PTX - 880		Ramadevi Nimmanapalli et al., Molecular Characterization and Sensitivity of STI-571 (Imatinib Mesylate, Gleevec)-resistant, Bcr-Abl-positive, Human Acute Leukemia Cells to SRC Kinase Inhibitor PD180970 and 17-Allylamino-17-demethoxygeldanamycin	10/15/2002		F, H, DUP
PTX - 881		Bhushan Nagar et al., Crystal Structures of the Kinase Domain of c-Abl in Complex with the Small Molecule Inhibitors PD173955 and Imatinib (STI-571) 62 Cancer Res. 4236 (2002)	8/1/2002		F, H, U, R, DUP
PTX - 882		David Wisniewski et al., Characterization of Potent Inhibitors of the Bcr-Abl and the c-Kit Receptor Tyrosine Kinases, 62 Cancer Research 4244 (2002)	8/1/2002		F, H, DUP
PTX - 883		U.S. Patent 8,119,649 B2	2/21/2012		F, H, DUP
PTX - 884		U.S. Patent 8,268,837 B2	9/18/2012		F, H, DUP
PTX - 885		Fahad A. Al-Obeidi & Kit S. Lam, Development of Inhibitors for Protein Tyrosine Kinases, 19 Oncogene 5690			F, H, U, R, DUP

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		(2000)			
PTX - 886		Thomas Schindler et al., Structural Mechanism for STI-571 Inhibition of Abelson Tyrosine Kinase, 289 Science 1938 (2000)	9/15/2000		F, H, U, R, DUP
PTX - 887		Robert A. Blake et al., SU6656, a Selective Src Family Kinase Inhibitor, Used To Probe Growth Factor Signaling, (2000) 9018			F, H, U, R, DUP
PTX - 888		Jurg Zimmermann et al., Potent and Selective Inhibitors of the Abl-Kinase: Phenylamino-Pyrimidine (PAP) Derivatives (1997)			F, H, U, R, DUP
PTX - 889		Uwe Trinks et al., Dianilinophthalimides: Potent and Selective, ATP-Competitive Inhibitors of the EGF-Receptor Protein Tyrosine Kinase, 37 J. Med. Chemistry 1015 (1994)			F, H, U, R, DUP
PTX - 890		Peter Traxler et al., Use of a Pharmacophore Model for the Design of EGF-R Tyrosine Kinase Inhibitors: 4-(Phenylamino)pyrazolo[3,4-d]pyrimidines, J. Med. Chem. 1997, 40, 3601-3616			F, H, U, R, DUP

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 891		Martin Missbach et al., Substituted 5,7-Diphenyl-pyrrolo[2,3d]pyrimidines: Potent Inhibitors of the Tyrosine Kinase c-Src, Bioorganic & Medicinal Chemistry Letters 10 (2000) 945-949	2/22/2000		F, H, U, R, DUP
PTX - 892		Eva Altmann et al., 7-Pyrrolidinyl- and 7-Piperidinyl-5-aryl-pyrrolo[2,3-dipyrimidines—Potent Inhibitors of the Tyrosine Kinase c-Src, Bioorganic & Medicinal Chemistry Letters 11 (2001) 853-856			F, H, U, R, DUP
PTX - 893		Leo Widler et al., 7-Alkyl- and 7-Cycloalkyl-5-aryl-pyrrolo[2,3-dipyrimidines—Potent Inhibitors of the Tyrosine Kinase c-Src, 11 Bioorganic & Med. Chemistry Letters 849 (2001)	2/2/2001		F, H, U, R, DUP
PTX - 894		Michael J. Mauro et al., STI571: Targeting BCR-ABL as Therapy for CML, The Oncologist 2001;6:233-238			F, H, DUP
PTX - 895		Gleevec Prescribing Information			F, H, U, R
PTX - 896		Mercedes E. Gorre et al., Clinical Resistance to STI-571 Cancer Therapy Caused by BCR-ABL Gene Mutation or Amplification, Science 293, 876 (2001)			F, H, U, R, DUP

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 897		Matthew B. Wilson et al., Selective pyrrolo-pyrimidine inhibitors reveal a necessary role for Src family kinases in Bcr — Abl signal transduction and onco genesis, Oncogene (2002) 21, 8075-8088			F, H, DUP
PTX - 898		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 899		INTENTIONALLY LEFT BLANK (DUPE OF PTX-053)			Exhibit not provided
PTX - 900		INTENTIONALLY LEFT BLANK (DUPE OF PTX-054)			Exhibit not provided
PTX - 901		Materials Considered			F, H, U, R
PTX - 902		INTENTIONALLY LEFT BLANK			
PTX - 903		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 904		INTENTIONALLY LEFT BLANK			Exhibit not provided
PTX - 905		Recordation Form Cover Sheet		PFE-BOS02787347 - 51	F, H, U, R
PTX - 906		Patent Assignment Cover Sheet with Exhibit, 503964145, 8/17/2016		PFE-BOS02787352 - 61	F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 907		USPTO, Assignment abstract of title for Application 10980097		PFE-BOS02787362	A, F, H, U, R
PTX - 908		Form-PTO-1595, 1-31-92		PFE-BOS02787363 - 67	F, H, U, R
PTX - 909		Patent Assignment, Certificate of Conversion from a Corporation to Limited Liability Company	11/9/2009	PFE-BOS02787368 - 78	A, F, H, U, R
PTX - 910		Patent Assignment Cover Sheet, Change of Address for Assignee, Doc Id 503962509		PFE-BOS02787379 - 97	A, F, H, U, R
PTX - 911		USPTO, Assignment abstract of title for Application 11478216		PFE-BOS02787398	A, F, H, U, R
PTX - 912		USPTO, Assignment abstract of title for Application 12139834		PFE-BOS02787399	A, F, H, U, R
PTX - 913		Contribution Agreement Novation Deed: Pfizer Pharmaceuticals LLC to PBG Puerto Rico LLC		PFE-BOS02791414 - 22	A, F, H, U, R
PTX - 914		License and Sublicense Novation Deed		PFE-BOS02791423 - 34	A, F, H, U, R
PTX - 915		Sublicense Agreement; PF Prism C.V. to Pfizer Asia Pacific PTE. LTD.		PFE-BOS02789707 - 38	A, F, H, U, R
PTX - 916		Sublicense Agreement; PF Prism C.V. to Pfizer Ireland Pharmaceuticals		PFE-BOS02789739 - 70	A, F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 917		Certificate of Conversion from a Corporation to Limited Liability Company; Certificate of Formation Wyeth Pharmaceuticals LLC		PFE-BOS01501393 - 98	A, F, H, U, R
PTX - 918		Email to Rasmussen with draft Drug Safety and Metabolism strategy for advancement of WAY-173606 to development track for oncology	8/2/2002	PFE-BOS01531445 - 48	Exhibit not provided
PTX - 919		Src Kinase Inhibitor - Oncology WAY-173606 Pre-Development	9/23/2002	PFE-BOS01607479 - 510	
PTX - 920		INTENTIONALLY LEFT BLANK			
PTX - 921		INTENTIONALLY LEFT BLANK			
PTX - 922		INTENTIONALLY LEFT BLANK			
PTX - 923		Provisional Application No. 60/517,819	11/6/2003	PFZFH0001249 - 99	
PTX - 924		Provisional Application No. 60/696,381	9/26/2005	PFZFH0001300 - 41	
PTX - 925	Ardnt Ex. 5; Boschelli, F. Ex. 8	Interoffice Correspondence - Highlights from Src Team Meeting, February 25, 2000 (PREVIOUSLY MARKED AS PTX-	3/4/2000	PFE-BOS01607243 - 48	F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		005)			
PTX - 926	Lucas Ex. 4	Highlights from Src Team Meeting, February 25, 2000 (PREVIOUSLY MARKED AS PTX-168)	3/4/2000	PFE-BOS01531771 - 76	F, H, U, R
PTX - 927	Golas Ex. 2	Interoffice Correspondence - Update for Src (PREVIOUSLY MARKED AS PTX-120)	5/30/2000	PFE-BOS01530958 - 59	F, H, U, R
PTX - 928	Boschelli, D. Ex. 39; Golas Ex. 3; Lucas Ex. 6	Interoffice Correspondence- Highlights from Src Team Meeting, January 31, 2001 (PREVIOUSLY MARKED AS PTX-048)	2/7/2001	PFE-BOS01531779 - 86	F, H, U, R
PTX - 929	Golas Ex. 4	Interoffice Correspondence - Highlights from Src Team Meeting, April 20, 2001 (PREVIOUSLY MARKED AS PTX-121)	4/26/2001	PFE-BOS01531788 -800	F, H, U, R
PTX - 930	Ardnt Ex. 6; Boschelli, F. Ex. 9; Gibbons Ex. 1; Lucas Ex. 7	Interoffice Correspondence - Synopsis from Src Team Meeting, August 17, 2001 (PREVIOUSLY MARKED AS PTX-006)	8/24/2001	PFE-BOS01868771 - 80	F, H, U, R
PTX - 931	Golas Ex. 5	Interoffice Correspondence - Highlights from Src Team Meeting, August 17, 2001 (PREVIOUSLY MARKED AS PTX-	8/24/2001	PFE-BOS01582578 - 87	F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		122)			
PTX - 932	Golas Ex. 6; Lucas Ex. 8	Interoffice Correspondence - Synopsis of the Src Team Meeting, October 19, 2001 (PREVIOUSLY MARKED AS PTX-123)	10/26/2001	PFE-BOS01582889 - 93	F, H, U, R
PTX - 933	Lucas Ex. 10	Synopsis of the Src Team Meeting, December 14, 2001 (PREVIOUSLY MARKED AS PTX-171)	12/28/2001	PFE-BOS01531809 - 16	F, H, U, R
PTX - 934	Ardnt. Ex 7; Boschelli, F. Ex. 10	Minutes for the Src kinase team meeting on May 24, 2002 (PREVIOUSLY MARKED AS PTX-007)	5/24/2002	PFE-BOS01864410 - 12	F, H, U, R
PTX - 935		Meeting Minutes - Src Kinase Project # 1098 (PREVIOUSLY MARKED AS PTX-920)	6/21/2002	PFE-BOS01864468 - 70	
PTX - 936		Meeting Minutes - Src Kinase Project # 1098 (Issued 7-19) (PREVIOUSLY MARKED AS PTX-921)	7/12/2002	PFE-BOS01864497 - 99	
PTX - 937		Meeting Minutes - Src Kinase Project # 1098 (Issued 8-22) (PREVIOUSLY MARKED AS PTX-	8/16/2002	PFE-BOS01864508 - 11	

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		922)			
PTX - 938	Boschelli, F. Ex. 11; Clarke Ex. 4; Feigelson Ex. 17; Tesconi 24	Internal Correspondence - Src Kinase Inhibitor: for use in Stroke and Oncology(WAY-173606) Pre-Development Team Meeting Minutes - October 16, 2002 (PREVIOUSLY MARKED AS PTX-055)	10/21/2002	PFE-BOS01593573 - 91	F, H, U, R
PTX - 939	Feigelson Ex. 16	Email from Yolanda Donate Subject: Minutes -10/16 Src for Stroke/Onc. Pre development Team Meeting (PREVIOUSLY MARKED AS PTX-113)	10/21/2002	PFE-BOS01593572	A, F, H, U, R
PTX - 940		Internal Correspondence - Src Kinase Inhibitor: for use in Stroke and Oncology (WAY-173606) Pre-Development Team Meeting Minutes - October 16, 2002 (PREVIOUSLY MARKED AS PTX-299)	10/21/2002	PRE-BOS01517163- 81	F, H, U, R
PTX - 941	Boschelli, F. Ex. 12	Minutes for Src team discovery meeting on October 18, 2002, (PREVIOUSLY MARKED AS PTX-056)	10/25/2002	PFE-BOS01616615 - 17	F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 942	Boschelli, F. Ex. 13; Clarke Ex. 5; Feigelson Ex. 18; Tesconi 25	Internal Correspondence - Src Kinase Inhibitor: for use in Stroke and Oncology (WAY-173606) Pre-Development Team Meeting Minutes November 12, 2002 (PREVIOUSLY MARKED AS PTX-057)	11/15/2002	PFE-BOS01593603 - 15	F, H, U, R
PTX - 943	Boschelli, F. Ex. 14; Clarke Ex. 6; Feigelson Ex. 19	Internal Correspondence - Src Kinase Inhibitor: for use in Stroke and Oncology (WAY-173606) Pre-Development Team Meeting Minutes December 5, 2002 (PREVIOUSLY MARKED AS PTX-058)	12/13/2002	PFE-BOS01593637 - 59	F, H, U, R
PTX - 944	Boschelli, F. Ex. 15; Clarke Ex. 7; Feigelson Ex. 20; Tesconi 26	Internal Correspondence - Src Kinase Inhibitor: for use in Stroke and Oncology (WAY-173606) Pre-Development Team Meeting Minutes January 13, 2003 (PREVIOUSLY MARKED AS PTX-059)	1/15/2003	PFE-BOS01593199 - 208	F, H, U, R
PTX - 945		Internal Correspondence - Src Kinase Inhibitor: for use in Stroke and Oncology (WAY-173606) Pre-Development Team Meeting Minutes January 13, 2003 (PREVIOUSLY MARKED AS PTX-300)	1/15/2003	PFE-BOS01633040 -49	F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 946	Ardnt Ex. 9; Boschelli, F. Ex. 16; Gibbons Ex. 6	Internal Correspondence - Summary of February 5, 2003 Src Kinase Program (PREVIOUSLY MARKED AS PTX-009)	2/12/2003	PFE-BOS01607606 - 09	F, H, U, R
PTX - 947	Boschelli, F. Ex. 17; Clarke Ex. 8; Feigelson Ex. 21; Tesconi 27	Internal Correspondence - Src Kinase Inhibitor: for use in Stroke and Onc. (WAY-173606) Pre-Development Team Meeting Minutes February 13, 2003 (PREVIOUSLY MARKED AS PTX-060)	2/19/2003	PFE-BOS01588107 - 113	F, H, U, R
PTX - 948	Ardnt Ex. 13; Boschelli, F. Ex. 18; Clarke Ex. 9; Feigelson Ex. 22; Gibbons Ex. 7; Tesconi 28	Internal Correspondence - Src Kinase Inhibitor: for use in Stroke and Onc. (WAY-173606) Pre-Development Team Meeting Minutes March 10, 2003 (PREVIOUSLY MARKED AS PTX-013)	3/19/2003	PFE-BOS01593298 - 309	F, H, U, R
PTX - 949		3/26/2003 Meeting Minutes of the Src Kinase Team (PREVIOUSLY MARKED AS PTX-902)	3/26/2003	PFE-BOS01865310 - 12	Exhibit not provided
PTX - 950	Boschelli, F. Ex. 19; Clarke Ex. 10; Feigelson Ex. 23; Tesconi 29	Internal Correspondence - Src Kinase Inh. for use in Stroke/Oncology (WAY-173606) Pre-development Team Meeting Minutes 4/2/03 (PREVIOUSLY MARKED AS PTX-	4/8/2003	PFE-BOS01593323 - 31	F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
		061)			
PTX - 951	Boschelli, F. Ex. 20; Clarke Ex. 11; Feigelson Ex. 24; Tesconi 30	Internal Correspondence - Src Kinase Inh, for use in Stroke/Oncology (WAY-173606) Pre-development Team Meeting Minutes 5/2/03 (PREVIOUSLY MARKED AS PTX-062)	5/8/2003	PFE-BOS01593338 - 45	F, H, U, R
PTX - 952		Meeting Minutes WAY-173606 Salt Selection (PREVIOUSLY MARKED AS PTX-325)	5/13/2003	PFE-BOS01681033	F, H, U, R
PTX - 953	Boschelli, F. Ex. 21; Clarke Ex. 12; Feigelson Ex. 25; Tesconi 31	Internal Correspondence - Src Kinase Inh. for use in Stroke/Oncology (WAY-173606) Pre-development Team Meeting Minutes 6/2/03 (PREVIOUSLY MARKED AS PTX-063)	6/5/2003	PFE-BOS01593349 - 61	F, H, U, R
PTX - 954		Internal Correspondence - Src Kinase Inh. for use in Stroke/Oncology (WAY-173606) Pre-development Team Meeting Minutes 6/2/03 (PREVIOUSLY MARKED AS PTX-301)	6/5/2003	PFE-BOS01516946 - 58	F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 955	Strong Ex. 3; Tesconi 22; Wen 7	Meeting Minutes - WAY-173606 Freebase polymotph / Salt Selection June 18, 2003 (PREVIOUSLY MARKED AS PTX-284)	6/25/2003	PFE-BOS01532477 - 78	F, H, U, R
PTX - 956	Boschelli, F. Ex. 22; Clarke Ex. 13; Feigelson Ex. 26	Internal Correspondence - Src Kinase Inh. for use in Stroke/Oncology (WAY-173606) Pre-development Team Meeting Minutes 7/2/03 (PREVIOUSLY MARKED AS PTX-064)	7/9/2003	PFE-BOS01593377 - 88	F, H, U, R
PTX - 957		Internal Correspondence - Src Kinase Inh. for use in Stroke/Oncology (WAY-173606) Pre-development Team Meeting Minutes 7/2/03 (PREVIOUSLY MARKED AS PTX-302)	7/9/2003	PFE-BOS01516974 - 85	F, H, U, R
PTX - 958		SKI-606 Oncology Global Strategy Team Meeting Agenda (PREVIOUSLY MARKED AS PTX-319)	8/1/2003	PFE-BOS01611617- 18	F, H, U, R
PTX - 959	Boschelli, F. Ex. 23; Clarke Ex. 14; Feigelson Ex. 27; Tesconi 32	Internal Correspondence - Src Kinase Inh. for use in Stroke (WAY-173606) Pre-development Team Meeting Minutes 8/6/03 (PREVIOUSLY MARKED AS PTX-065)	8/14/2003	PFE-BOS01593409 - 23	F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 960	Boschelli, F. Ex. 24	SKI-606 Bosutinib Biomarker Subteam Meeting Minutes (PREVIOUSLY MARKED AS PTX-066)	8/20/2003	PFE-BOS01632274 - 76	F, H, U, R
PTX - 961	Clarke Ex. 15	Internal Correspondence - SKI-606 Oncology Global Development Team August 14, 2003, Meeting Minutes (PREVIOUSLY MARKED AS PTX-078)	8/22/2003	PFE-BOS02605633 - 38	F, H, U, R
PTX - 962	Feigelson Ex. 28	Internal Correspondence - Src Kinase Inh. for use in Stroke (WAY-173606) Pre-development Team Meeting Minutes 9/11/03 (PREVIOUSLY MARKED AS PTX-114)	9/16/2003	PFE-BOS01517047 - 55	F, H, U, R
PTX - 963	Clarke Ex. 16	Internal Correspondence - SKI-606 Oncology Global Development Team September 11, 2003, Meeting Minutes (PREVIOUSLY MARKED AS PTX-079)	9/19/2003	PFE-BOS02689485 - 91	F, H, U, R
PTX - 964	Feigelson Ex. 29	Internal Correspondence - Src for Stroke Pre-development Team Meeting Agenda 10/9/03 (PREVIOUSLY MARKED AS PTX-115)	10/3/2003	PFE-BOS01517064 - 66	F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 965	Clarke Ex. 17	Internal Correspondence - SKI-606 Oncology Global Development Team October 15, 2003, Meeting Minutes (PREVIOUSLY MARKED AS PTX-080)	10/15/2003	PFE-BOS02694116 - 22	F, H, U, R
PTX - 966		SKI-606 Oncology Global Development Team Meeting Agenda (PREVIOUSLY MARKED AS PTX-321)	11/4/2003	PFE-BOS01611749 - 50	F, H, U, R
PTX - 967	Feigelson Ex. 30	Internal Correspondence - Src for Stroke Pre-development Team Meeting Agenda 11/11/03 (PREVIOUSLY MARKED AS PTX-116)	11/5/2003	PFE-BOS01517068 - 70	F, H, U, R
PTX - 968	Clarke Ex. 18	Internal Correspondence - SKI-606 Oncology Global Development Team November 11, 2003, Meeting Minutes (PREVIOUSLY MARKED AS PTX-081)	11/18/2003	PFE-BOS02694602 - 08	F, H, U, R
PTX - 969	Feigelson Ex. 31	PowerPoint - SKI-606 End of Phase 1 Meeting - Chemical and Pharmaceutical Development 27 February 2006 (PREVIOUSLY MARKED AS PTX-117)	2/27/2006	PFE-BOS01683146 - 323	A, F, H, U, R

Plaintiff's Trial Exhibit No.	Deposition Exhibit No.	Evidence Offered by Plaintiff	Date	Document No.	Sun's Objections
PTX - 970		Latest produced version of Sun's label from December, 2018	12/00/2018	SUN-BOS0089353 - 78	
PTX - 971		Meeting Minutes : Src Kinase 1098 (2/15/2002)	2/15/2002	PFE-BOS01868847 - 49	
PTX - 972		Meeting Minutes : Src Kinase 1098 (3/14/2002)	3/14/2002	PFE-BOS01864132 - 34	

EXHIBIT 11

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH LLC, WYETH PHARMACEUTICALS)	
LLC, PF PRISM C.V., PBG PUERTO RICO LLC,)	
and PF PRISM IMB B.V.,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 16-1305 (RGA)
)	
SUN PHARMACEUTICAL INDUSTRIES)	(Consolidated)
LIMITED, and SUN PHARMACEUTICAL)	
INDUSTRIES, INC.,)	
)	
Defendants.)	
)	

DEFENDANTS' TRIAL EXHIBIT LIST

ABBREVIATION AND FEDERAL RULE OF EVIDENCE
KEY TO THE OBJECTIONS

ABBREVIATION	OBJECTION	APPLICABLE RULE(S)
A	Requires authentication or identification	FRE 901
B	Best evidence rules prohibit introduction	FRE 1001-1002
C	Improper compilation of separate documents	FRE 403, 901
D	Improper designation (designation is neither a question or testimony)	FRE 401, 402
E	Improper examination (vague, ambiguous, loaded, leading, etc.)	FRE 402, 403, 602, 611
F	Lack of foundation/personal knowledge (including calls for speculation)	FRE 402, 403, 602, 611
H	Hearsay if offered for the truth of the matter asserted	FRE 801, 802
I	Incomplete document or testimony	FRE 106, 403
M	Offer or discussion for settlement or compromise	FRE 408
N	Exhibit not produced in discovery	FRE 403
O	Improper opinion testimony	FRE 701-704
P	Privileged or attorney work product	FRE 501, 502
PP	Printed Publication (potential hearsay)	FRE 801, 802
R	Lack of relevance	FRE 401, 402
S	Summary requiring underlying data or information	FRE 1006
T	Beyond the scope of the Rule 30(b)(6) topic for which a witness has been designated	FRE 602, FRCP 30(b)(6)
U	Unduly prejudicial, wasteful, confusing, misleading or cumulative	FRE 403

Exhibit 11

<u>Proposed Exhibit No.</u>	<u>Cited in</u>	<u>Source Ex. #</u>	<u>Document Title / Description</u>	<u>Bates Range</u>	<u>Also Cited In</u>	<u>Plaintiffs' Objections</u>
DTX-001			Certified U.S. Patent 7,417,148 B2	PFZFH000119 8 - 208	Lindsley Dep. Ex. 1; Shah Infringement Report Ex. A; Shah Validity Report Ex. A; Levis Validity Report Ex. A; Murcko Responsive Report Ex. A	
DTX-002			Certified File Wrapper for U.S. Patent 7,417,148 B2	PFZFH000001 - 473		
DTX-003			Certified U.S. Patent 7,767,678 B2	PFZFH000122 0 - 239	Balaji Ex. 4; Chyall Opening Report Ex. A; Chyall Validity Report Ex. A	
DTX-004			Certified File Wrapper for Certified U.S. Patent 7,767,678 B2	PFZFH000474 - 1020		

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<u>Proposed Exhibit No.</u>	<u>Cited in</u>	<u>Source Ex. #</u>	<u>Document Title / Description</u>	<u>Bates Range</u>	<u>Also Cited In</u>	<u>Plaintiffs' Objections</u>
DTX-005			Certified U.S. Patent 7,919,625 B2	PFZFH0001209 - 219	Lindsley Dep. Ex. 2; Shah Infringement Report Ex. B; Shah Validity Report Ex. B; Trout Responsive Report Ex. A; Murcko Responsive Report Ex. A; Levis Validity Report Ex. B	
DTX-006			Certified File Wrapper for Certified U.S. Patent 7,919,625 B2	PFZFH001021 - 197		
DTX-007	Deposition of Frank Boschelli	1	Defendants' Amended Notice of Deposition of Plaintiffs' Pursuant to Federal Rule Civil Procedure 30(b)(6)	Exhibit 1 to the Deposition of Frank Boschelli		
DTX-008	Deposition of Frank Boschelli	2	Plaintiffs' Responses and Objections to Defendants' Notice of Deposition Pursuant to Federal Rules Civil Procedure 30(b)(6)	Exhibit 2 to the Deposition of Frank Boschelli		
DTX-009	Deposition of Frank Boschelli	3	Frank Boschelli's curriculum vitae	PFE-BOS01773866 - 874		

Exhibit 11

<u>Proposed Exhibit No.</u>	<u>Cited in</u>	<u>Source Ex. #</u>	<u>Document Title / Description</u>	<u>Bates Range</u>	<u>Also Cited In</u>	<u>Plaintiffs' Objections</u>
DTX-010	Deposition of Frank Boschelli	4	U.S. Patent 7,417,148 B2	SUN-BOS0029527 - 536	Arndt Dep. Ex. 2	
DTX-011	Deposition of Frank Boschelli	5	U.S. Patent 7,919,625 B2	SUN-BOS0029518 - 526	Arndt Dep. Ex. 3	
DTX-012	Deposition of Frank Boschelli	6	Email re: manuscript describing CML results	PFE-BOS01772244	Lucas Dep. Ex. 12	
DTX-013	Deposition of Frank Boschelli	7	Manuscript describing CML results	PFE-BOS01772245 - 273	Lucas Dep. Ex. 13; Gibbons Dep. Ex. 4	
DTX-014	Deposition of Frank Boschelli	8	Highlights from Src Team Meeting, February 25, 2000	PFE-BOS01607243 - 248	Arndt Dep. Ex. 5	
DTX-015	Deposition of Frank Boschelli	9	Synopsis of the Src Team Meeting, August 17, 2001	PFE-BOS01868771 - 780	Arndt Dep. Ex. 6; Lucas Dep. Ex. 7	
DTX-016	Deposition of Frank Boschelli	10	Minutes for the Src kinase team meeting on May 24, 2002	PFE-BOS01864410 - 412	Arndt Dep. Ex.7	
DTX-017	Deposition of Frank Boschelli	11	Src Kinase Inhibitor: for use in Stroke and Oncology (WAY-173606) Pre-Development Team Meeting Minutes - October 16, 2002	PFE-BOS01593573 - 591	Clark Dep. Ex. 4; Feigelson Dep. Ex. 17; Testoni Dep. Ex. 24	
DTX-018	Deposition of Frank Boschelli	12	Src team discovery team minutes for October 25, 2002	PFE-BOS01616615 - 617		

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<u>Proposed Exhibit No.</u>	<u>Cited in</u>	<u>Source Ex. #</u>	<u>Document Title / Description</u>	<u>Bates Range</u>	<u>Also Cited In</u>	<u>Plaintiffs' Objections</u>
DTX-019	Deposition of Frank Boschelli	13	Minutes of a Src kinase inhibitor for the use of stroke/oncology, predevelopment meeting on November 15, 2002	PFE-BOS01593603 - 615	Clark Dep. Ex. 5; Feigelson Dep. Ex. 18; Tesconi Dep. Ex. 25	
DTX-020	Deposition of Frank Boschelli	14	Meeting minutes for the Src kinase inhibitor for stroke/oncology for predevelopment on December 13, 2002	PFE-BOS01593637 - 659	Clark Dep. Ex. 6; Feigelson Dep. Ex. 19	
DTX-021	Deposition of Frank Boschelli	15	Minutes for the Src kinase inhibitor for use in stroke/oncology, predevelopment team on January 15, 2003	PFE-BOS01593199 - 208	Clark Dep. Ex. 7; Feigelson Dep. Ex. 20; Tesconi Dep. Ex. 26	
DTX-022	Deposition of Frank Boschelli	16	Wyeth Research, 2/12/03 Memo to Beth Rasmussen from Daryl Sonnichsen, Summary of February 5, 2003 Src Kinase Program	PFE-BOS01607606 - 609	Arndt Dep. Ex. 9; Gibbons Dep. Ex. G	
DTX-023	Deposition of Frank Boschelli	17	Meeting minutes for the Src kinase inhibitor for use in stroke/oncology, the predevelopment team on February 29, 2003	PFE-BOS01588107 - 113	Feigelson Dep. Ex. 21; Clarke Dep. Ex. 8; Tesconi Dep. Ex. 27	
DTX-024	Deposition of Frank Boschelli	18	Wyeth 3/19/03 Memo to Distribution from B. Rasmussen, Src Kinase Inhibitor: For Use in Stroke and Onc, WAY-173606 Predevelopment Team Meeting Minutes, March	PFE-BOS01593298 - 309	Arndt Dep. Ex. 13; Feigelson Dep. Ex. 22; Clark Dep. Ex. 9; Tesconi Dep. Ex. 28; Gibbons Dep. Ex. 7	

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DTX-025	Deposition of Frank Boschelli	19	Minutes to Src kinase inhibitor team for use in stroke/oncology, the predevelopment team April 8, 2003	PFE-BOS01593323 - 331	Feigelson Dep. Ex. 23; Clark Dep. Ex. 10; Tesconi Dep. Ex. 29	
DTX-026	Deposition of Frank Boschelli	20	Minutes for the Src kinase inhibitor for use in stroke/oncology, predevelopment team May 8, 2003	PFE-BOS01593338 - 345	Feigelson Dep. Ex. 24; Clark Dep. Ex. 11; Tesconi Dep. Ex. 30	
DTX-027	Deposition of Frank Boschelli	21	Minutes for the Src kinase inhibitor program for use in stroke/oncology, predevelopment team on June 5, 2003	PFE-BOS01593349 - 361	Feigelson Dep. Ex. 25; Clark Dep. Ex. 12; Tesconi Dep. Ex. 21	
DTX-028	Deposition of Frank Boschelli	22	Src Kinase inhibitor team minutes for stroke/oncology, the predevelopment team on July 9, 2003	PFE-BOS01593377 - 388	Feigelson Dep. Ex. 26; Clark Dep. Ex. 13	
DTX-029	Deposition of Frank Boschelli	23	Minutes of the Src kinase inhibitor program for stroke, predevelopment minutes on August 14, 2003	PFE-BOS01593409 - 423	Feigelson Dep. Ex. 27; Clark Dep. Ex. 14; Tesconi Dep. Ex. 32	
DTX-030	Deposition of Frank Boschelli	24	Minutes of Bosutinib Biomarker Subteam Meeting on August 20, 2003	PFE-BOS01632274 - 276		

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<u>Proposed Exhibit No.</u>	<u>Cited in</u>	<u>Source Ex. #</u>	<u>Document Title / Description</u>	<u>Bates Range</u>	<u>Also Cited In</u>	<u>Plaintiffs' Objections</u>
DTX-031	Deposition of Frank Boschelli	25	E-mail chain Re: Src inhibitors	PFE-BOS01534204 - 205	Arndt Dep. Ex. 14	
DTX-032	Deposition of Frank Boschelli	26	ASH Abstract	PFE-BOS01534206	Arndt Dep. Ex. 15; F. Druker Dep. Ex. 12	
DTX-033	Deposition of Frank Boschelli	27	Nicholas J. Donato et al., Novel Tyrosine Kinase Inhibitors Suppress BCR-ABL Signaling and Induce Apoptosis in STI-571 Sensitive and Resistant CML Cells, 100 BLOOD 370a (2002)	SUN-BOS0012019 - 020	Lindsley Opening Report Ex. H	PP
DTX-034	Deposition of Frank Boschelli	28	D. Boschelli et al., Optimization of 4-Phenylamino-3-quinolinecarbonitriles as Potent Inhibitors of Src Kinase Activity, J. Med. Chem. 44:3965 (2001)	SUN-BOS0011849 - 861	Nadkarni Dep. Ex. 36; Lindsley Opening Report Ex. D	PP
DTX-035	Deposition of Frank Boschelli	29	Paper describing the activity of SKI-606 in CML studies	PFE-BOS00252107 - 113		PP
DTX-036	Deposition of Diane H. Boschelli	30	Resume of Diane Harris Boschelli	PFE-BOS01585503 - 515		

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DTX-037	Deposition of Diane H. Boschelli	31	U. S. Patent 7,417,148 B2	Exhibit 31 to the Deposition of Diane H. Boschelli	Druker Dep. Ex. 6; Nadkarni Dep. Ex. 7; Clarke Dep. Ex. 2; Golas Dep. Ex. 7; Tesconi Dep. Ex. 3; Feigelson Dep. Ex. 12; Lucas Dep. Ex. 2	
DTX-038	Deposition of Diane H. Boschelli	32	U. S. Patent 7,767,678 B2	Exhibit 32 to the Deposition of Diane H. Boschelli	Nadkarni Dep. Ex. 8; Feigelson Dep. Ex. 3; Tesconi Dep. Ex. 5	
DTX-039	Deposition of Diane H. Boschelli	33	Discovery Prioritization Process - Program Updates	PFE-BOS01532210 - 211		
DTX-040	Deposition of Diane H. Boschelli	34	Application for Discovery Team Status	PFE-BOS02611765 - 777		
DTX-041	Deposition of Diane H. Boschelli	35	Application for Team Status, Small Molecules - Pre-Development	PFE-BOS02612069 - 082		
DTX-042	Deposition of Diane H. Boschelli	36	Src Kinase Inhibitor – Oncology WAY-173606 Pre-Development, 9-23-02	PFE-BOS01696030 - 061		

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<u>Proposed Exhibit No.</u>	<u>Cited in</u>	<u>Source Ex. #</u>	<u>Document Title / Description</u>	<u>Bates Range</u>	<u>Also Cited In</u>	<u>Plaintiffs' Objections</u>
DTX-043	Deposition of Diane H. Boschelli	37	Bosutinib: From Yeast to the Clinic	PFE-BOS01633993 - 4031		
DTX-044	Deposition of Diane H. Boschelli	38	Diane H. Boschelli et al., Optimization of 4-Phenylamino-3-quinolinecarbonitriles as Potent Inhibitors of Src Kinase Activity, 44 J. Med. Chemistry 3965 (2001)	Exhibit 38 to the Deposition of Diane H. Boschelli	Tesconi Dep. Ex. 15; Feigelson Dep. Ex. 7; Lindsley Dep. Ex. 15; Murcko Resp Rep Ex E; Gibbons Dep. Ex. 2; Shah Validity Report Ex. MMM; Lindsley Reply Report Ex. B; Trout Responsive Report Ex. B	PP
DTX-045	Deposition of Diane H. Boschelli	39	Highlights from Src Team Meeting, January 31, 2001	PFE-BOS01531779 - 786	Golas Dep. Ex. 3; Lucas Dep. Ex. 6	
DTX-046	Deposition of Diane H. Boschelli	40	International Publication Number WO 03/093242 A1	SUN-BOS0012482 - 573		PP

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DTX-047	Deposition of Bharati Nadkarni	1	Plaintiffs' Notice of Deposition of Bharati Nadkarni	Exhibit 1 to the Deposition of Bharati Nadkarni		
DTX-048	Deposition of Bharati Nadkarni	2	Plaintiffs' Notice of Deposition of Sun Pharmaceutical Industries Limited and Sun Pharmaceutical Industries, Inc., Pursuant to Fed. R. Civ. P. 30(b)(6)	Exhibit 2 to the Deposition of Bharati Nadkarni		
DTX-049	Deposition of Bharati Nadkarni	3	Plaintiffs' Second Notice of Deposition of Sun Pharmaceutical Industries Limited and Sun Pharmaceutical Industries, Inc., Pursuant to Fed. R. Civ. P. 30(b)(6)	Exhibit 3 to the Deposition of Bharati Nadkarni		
DTX-051	Deposition of Bharati Nadkarni	5	Application to Market a New or Abbreviated New Drug or Biologic for Human Use	SUN-BOS0084425 - 429		
DTX-052	Deposition of Bharati Nadkarni	6	Statements of Certification Under Section 505(j)(2)(A)(vii) and 21 CFR 314.94(a)(12)	SUN-BOS0089229 - 236		
DTX-053	Deposition of Bharati Nadkarni	9	U.S. Patent 7,919,625 B2	Exhibit 9 to the Deposition of Bharati Nadkarni	Druker Dep. Ex. 7; Feigelson Dep. Ex. 13; Clarke Dep. Ex. 3; Golas Dep. Ex. 8; Lucas Dep. Ex. 3; Tesconi Dep. Ex. 4	

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DTX-054	Deposition of Bharati Nadkarni	10	Proposed Label for Sun's Bosutinib ANDA submitted to the FDA in July 2018	SUN-BOS0088887 - 913	Chyall Opening Report Ex. M; Shah Infringement Report Ex. Y	
DTX-055	Deposition of Bharati Nadkarni	11	Bottle Labels for 100mg and 500mg Sun Bosutinib Tablets	SUN-BOS0024670 - 671		
DTX-056	Deposition of Bharati Nadkarni	12	Sun's ANDA Module 2.3 Quality Overall Summary	SUN-BOS0013179 - 343	Chyall Opening Report Ex. N; Shah Infringement Report Ex. Z	
DTX-057	Deposition of Bharati Nadkarni	13	Errata 1 to Development Report – Bosutinib Tablet 100/500mg Market-USA	SUN-BOS0000561 - 636		
DTX-058	Deposition of Bharati Nadkarni	14	A Study to Evaluate the Relative Bioavailability of a Test formulation of Bosutinib 100 mg Tablets (Sun Pharmaceutical Industries Limited, India) compared to BOSULIF® (bosutinib monohydrate) Tablets [EQ 100 mg bosutinib] (Pfizer Labs) in Healthy Adult Subjects under Fasted Conditions	SUN-BOS0004030 - 107		

Exhibit 11

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DTX-059	Deposition of Bharati Nadkarni	15	A Study to Evaluate the Relative Bioavailability of a Test Formulation of Bosutinib 100 mg Tablets (Sun Pharmaceutical Industries Limited, India) compared to BOSULIFR (bosutinib monohydrate) Tablets [EQ 100 mg bosutinib] (Pfizer Labs) in Healthy Adult Subjects under Fed Conditions	SUN-BOS0004663 - 738		
DTX-060	Deposition of Bharati Nadkarni	16	Description of the Active Ingredient in Sun's ANDA included in the ANDA Dossier	SUN-BOS0016165 - 166		
DTX-061	Deposition of Bharati Nadkarni	17	Specification for MSN's Bosutinib	SUN-BOS0016179 - 186		
DTX-062	Deposition of Bharati Nadkarni	18	MSN Document Provided to FDA in Connection to ANDA 209577	SUN-BOS0032408 - 434		
DTX-063	Deposition of Bharati Nadkarni	19	Sun's May 24, 2016 Minutes of Product Review Meeting	SUN-BOS0084327 - 330	Chyall Opening Report Ex. P	
DTX-064	Deposition of Bharati Nadkarni	20	MSN Bosutinib Monohydrate (Form-I)	SUN-BOS0082075 - 076		
DTX-065	Deposition of Bharati Nadkarni	21	Bosutinib Monohydrate Form 1 MSN Laboratories Private Limited, Section 32S3 Characterization	SUN-BOS0082092 - 119		

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DTX-066	Deposition of Bharati Nadkarni	22	Bosutinib Monohydrate (Form-1) MSN Laboratories Private Limited, Section H – Stress Study for Polymorphic Identification by PXRD	SUN-BOS0082974 - 3000		
DTX-067	Deposition of Bharati Nadkarni	23	Regulatory Expectations – Bosutinib Tablets, 100mg and 500mg	SUN-BOS0033581 - 585	Chyall Opening Report Ex. Q	
DTX-068	Deposition of Bharati Nadkarni	24	Email from Vandana Gupta to Amit Kumar, CC Meenakshi Jain, Satyananda Misra, Ravindra Agarwal, Preeti Khatkar, Sunita Narang, Puneet Kumar Gupta, RE Bosutinib Tablets 100/500mg, dated May 7, 2016	SUN-BOS0040769 - 772		
DTX-069	Deposition of Bharati Nadkarni	25	Email from Preeti Khatkar to Amit Kumar, CC Meenakshi Jain, Puneet Kumar Gupta, Satyananda Misra, Neelam Tarani, Ghanshyam Panjwani, Ravindra Agarwal, RE !! Activity to be performed on: Document Revision 2015-09-25	SUN-BOS0041474 - 476	Chyall Opening Report Ex. R	
DTX-070	Deposition of Bharati Nadkarni	26	Department of Health and Human Services' Information Request to Sun Pharmaceutical Industries, Inc., in connection to ANDA 209577, dated April 4, 2017	SUN-BOS0025648 - 652		
DTX-071	Deposition of Bharati Nadkarni	27	Sun's Response to FDA Information Request , dated April 4, 2017	SUN-BOS0043277 - 293	Chyall Opening Report Ex. T	

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<u>Proposed Exhibit No.</u>	<u>Cited in</u>	<u>Source Ex. #</u>	<u>Document Title / Description</u>	<u>Bates Range</u>	<u>Also Cited In</u>	<u>Plaintiffs' Objections</u>
DTX-072	Deposition of Bharati Nadkarni	28	Response to Information Request, dated April 4, 2017	SUN-BOS0025024 - 038		
DTX-073	Deposition of Bharati Nadkarni	29	MSN Laboratories Private Limited Response to ANDA Deficiency Comments Received from Sun Pharmaceutical Industries Limited	SUN-BOS0034009 - 131		
DTX-074	Deposition of Bharati Nadkarni	30	Department of Health and Human Services' Complete Response to Sun Pharmaceutical Industries, Inc., in connection to ANDA 209577, dated November 29, 2017	SUN-BOS0088869 - 874	Chyall Opening Report Ex. S	
DTX-075	Deposition of Bharati Nadkarni	31	Response to Complete Response Letter dated November 29, 2017	SUN-BOS0088991 - 996		
DTX-076	Deposition of Bharati Nadkarni	32	MSN Laboratories Compilation with Regard to Bosutinib PXR	SUN-BOS0088783 - 796		
DTX-077	Deposition of Bharati Nadkarni	33	XRPD Patterns generated by Sun of Samples of Sun's ANDA Products	SUN-BOS0024859 - 977	Chyall Opening Report Ex. W;	
DTX-078	Deposition of Bharati Nadkarni	34	MSN Laboratories Notification Letter to Sun Pharmaceuticals, dated April 12, 2018	SUN-BOS0088777 - 782		

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DTX-079	Deposition of Bharati Nadkarni	35	Analytical Test Procedure Details for Bosutinib	SUN-BOS0088619 - 670		
DTX-080	Deposition of Bharati Nadkarni	37	Sun Pharmaceutical Industries, Inc.'s, Notice of Paragraph IV Certification Regarding U.S. Patent No. 7,767,678 to Wyeth Pharmaceuticals, Inc., and Wyeth LLC, dated November 11, 2016	PFE-BOS02601183 - 203		
DTX-081	Deposition of Bharati Nadkarni	38	Sun Pharmaceutical Industries, Inc.'s, Notice of Paragraph IV Certification Regarding U.S. Patent No. 7,417,148 to Wyeth Pharmaceuticals, Inc., and Wyeth LLC, dated August 16, 2017	PFE-BOS02601157 - 182	Shah Infringement Report Ex. BB	
DTX-082	Deposition of Bharati Nadkarni	39	Cover Letter Enclosing Sun Pharmaceutical's Production of Bosutinib Samples Pursuant to Offer of Confidential Access to Pfizer, dated December 15, 2016	Exhibit 39 to the Deposition of Bharati Nadkarni		
DTX-083	Deposition of Bharati Nadkarni	40	Cover Letter enclosing Sun Pharmaceutical's Production of Samples Pursuant to Protective Order to Pfizer, dated September 26, 2018	Exhibit 40 to the Deposition of Bharati Nadkarni		
DTX-084	Deposition of Bharati Nadkarni	41	Executed Batch Records Regarding ANDA Submission	SUN-BOS0074220 - 228		

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DTX-085	Deposition of Gregg Feigelson	1	Amended Notice of Deposition	Exhibit 1 to the Deposition of Gregg Feigelson		
DTX-086	Deposition of Gregg Feigelson	2	Amended Notice of Deposition	Exhibit 2 to the Deposition of Gregg Feigelson		
DTX-087	Deposition of Gregg Feigelson	8	SKI-606 Technical Review 1	PFE-BOS01683588 - 620		
DTX-088	Deposition of Gregg Feigelson	9	Plaintiffs' Supplemental Objections and Responses - Defendants' First Set of Joint Interrogatories	Exhibit 9 to the Deposition of Gregg Feigelson		
DTX-089	Deposition of Gregg Feigelson	10	Laboratory Notebook L23445	PFE-BOS02575275 - 486		
DTX-090	Deposition of Gregg Feigelson	11	Laboratory Notebook L27546	PFE-BOS02545487 - 690		
DTX-091	Deposition of Gregg Feigelson	14	Plaintiffs' Responses and Objections - Defendants' Notice of Deposition	Exhibit 14 to the Deposition of Gregg Feigelson		

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DTX-092	Deposition of Gregg Feigelson	15	Email String re: Wyeth v. Alembic depositions	Exhibit 15 to the Deposition of Gregg Feigelson		
DTX-093	Deposition of Gregg Feigelson	16	Email dated 10/21/02	PFE-BOS01593572		
DTX-094	Deposition of Gregg Feigelson	28	Team Meeting Minutes dated 9/16/03	PFE-BOS01517047 - 055		
DTX-095	Deposition of Gregg Feigelson	29	Team Meeting Minutes dated 10/3/03	PFE-BOS01517064 - 066		
DTX-096	Deposition of Gregg Feigelson	30	Team Meeting Minutes dated 10/5/03	PFE-BOS01517068 - 070		
DTX-097	Deposition of Gregg Feigelson	31	SKI-606 End of Phase 1 Meeting PowerPoint	PFE-BOS01683146 - 323		
DTX-098	Deposition of Jennifer Golas	1	Curriculum vitae of Jennifer M. Golas	PFE-BOS01742533 - 536		
DTX-099	Deposition of Jennifer Golas	2	Wyeth interoffice correspondence dated May 30, 2000	PFE-BOS01530958 - 959		
DTX-100	Deposition of Jennifer Golas	4	Wyeth interoffice correspondence dated April 26, 2001	PFE-BOS01531788 - 800		

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DTX-101	Deposition of Jennifer Golas	5	Wyeth interoffice correspondence dated August 24, 2001	PFE-BOS01582578 - 587		
DTX-102	Deposition of Jennifer Golas	6	Wyeth interoffice correspondence dated October 26, 2001	PFE-BOS01582889 - 893		
DTX-103	Deposition of Jennifer Golas	9	Article from Cancer Research dated January 15, 2003	Exhibit 9 to the Deposition of Jennifer Golas		PP
DTX-104	Deposition of Brian Druker	1	Notice of subpoena	Exhibit 1 to the Deposition of Brian Druker		
DTX-105	Deposition of Brian Druker	2	Documents in response to request number 3	Exhibit 2 to the Deposition of Brian Druker		
DTX-106	Deposition of Brian Druker	3	Documents in response to request number 1	Exhibit 3 to the Deposition of Brian Druker		

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DTX-107	Deposition of Brian Druker	4	Documents in response to request number 2	Exhibit 4 to the Deposition of Brian Druker		
DTX-108	Deposition of Brian Druker	5	Frank Boschelli et al., Dual Src/Abl Kinase Inhibitor Causes Regression of CML Xenografts in Nude Mice, 100 BLOOD 786a (2002)	Exhibit 5 to the Deposition of Brian Druker		C, PP
DTX-109	Deposition of Brian Druker	8	10/08/2002 e-mail	PFE-BOS02768294		
DTX-110	Deposition of Brian Druker	9	E-mail string	PFE-BOS02768296 - 297		
DTX-111	Deposition of Brian Druker	10	Proposal	PFE-BOS02768298 - 299		
DTX-112	Deposition of Brian Druker	11	E-mail string	PFE-BOS01611076 - 077		
DTX-113	Deposition of Brian Druker	13	E-mail string	PFE-BOS01566859		

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DTX-114	Deposition of Brian Druker	14	E-mail string	PFE-BOS02768289 - 292		
DTX-115	Deposition of Kim T. Arndt	1	Curriculum vitae of Dr. Kim T. Arndt	PFE-BOS01502593 - 597		
DTX-116	Deposition of Kim T. Arndt	4	Article entitled "Optimization of 4-phenylamino-3-quinoliner carbonitriles as Potent Inhibitors of Src Kinase in Activity"	Exhibit 4 to the Deposition of Kim T. Arndt		PP
DTX-117	Deposition of Kim T. Arndt	8	Presentation called Kinases in Oncology	PFE-BOS02664492 - 436		
DTX-118	Deposition of Kim T. Arndt	10	E-mail from Kim Arndt to Frank Boschelli	PFE-BOS01598733		
DTX-119	Deposition of Kim T. Arndt	11	Summary of February 5, 2003, Src Kinase Program Discussion	PFE-BOS01598734 - 738		
DTX-120	Deposition of Kim T. Arndt	12	Memo describing Src Kinase program discussion on February 5	PFE-BOS1532072 - 073		
DTX-121	Deposition of Hong Wen	1	Wen Subpoena	Exhibit 1 to the Deposition of Hong Wen		
DTX-122	Deposition of Hong Wen	2	Defendants' Amended Notice of Deposition of Hong Wen	Exhibit 2 to the Deposition of Hong Wen		

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DTX-123	Deposition of Hong Wen	7	WAY-173606 Meeting Minutes	PFE-BOS01532477 - 478		
DTX-124	Deposition of Hong Wen	8	SKI-606 Chemical Development Status	PFE-BOS01680541 - 546		
DTX-125	Deposition of Hong Wen	9	Technical Memo	PFE-BOS01850858 - 868		
DTX-126	Deposition of Hong Wen	10	Above and Beyond Award Nomination	PFE-BOS01754033 - 035		
DTX-127	Deposition of Hong Wen	11	Laboratory Notebook L-24710	PFE-BOS02594088 - 299		
DTX-128	Deposition of Hong Wen	12	Laboratory Notebook L-24711	PFE-BOS02594300 - 510		
DTX-129	Deposition of Hong Wen	13	Laboratory Notebook L-26019	PFE-BOS02593975 - 4087		
DTX-130	Deposition of Hong Wen	14	Email to Sherry Ku and Marc	PFE-BOS01856949		
DTX-131	Deposition of Edward Gramling	1	Defendants' 30(b)(6) Notice	Exhibit 1 to the Deposition of Edward Gramling		

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DTX-133	Deposition of Edward Gramling	3	License Agreement	PFE-BOS00000018 - 050		
DTX-134	Deposition of Edward Gramling	4	Plaintiffs' Supplemental Objections and Responses to Defendants' Joint Interrogatory Number 9	Exhibit 4 to the Deposition of Edward Gramling		
DTX-135	Deposition of Edward Gramling	5	Contribution Agreement	PFE-BOS00000001 - 005		
DTX-136	Deposition of Edward Gramling	6	License Agreement between Wyeth LLC to Wyeth Holdings LLC	PFE-BOS02787310 - 325		
DTX-137	Deposition of Edward Gramling	7	Amendment to License Agreement	PFE-BOS02787344 - 346		
DTX-138	Deposition of Edward Gramling	8	License and Sublicense Novation Deed	PFE-BOS00000006 - 017		

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DTX-140	Deposition of Edward Gramling	10	Second Amendment to License Agreement	PFE-BOS02787289 - 309		
DTX-141	Deposition of Judy Lucas	1	Resume of Judy Lucas	PFE-BOS1771581 - 584		
DTX-142	Deposition of Judy Lucas	4	Wyeth interoffice correspondence dated March 4, 2000	PFE-BOS01531771 - 776		
DTX-143	Deposition of Judy Lucas	5	Wyeth interoffice correspondence dated September 28, 2000	PFE-BOS01531045 - 049		
DTX-144	Deposition of Judy Lucas	8	Wyeth interoffice correspondence dated October 26, 2001	PFE-BOS01582889 - 893		
DTX-145	Deposition of Judy Lucas	9	Testing charts	PFE-BOS02760555 - 561		
DTX-146	Deposition of Judy Lucas	10	Wyeth interoffice correspondence dated December 28, 2001	PFE-BOS01531809 - 816		
DTX-147	Deposition of Judy Lucas	11	Testing worksheet	PFE-BOS02730857		

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DTX-148	Deposition of Judy Lucas	14	Abstract from Cancer Research, volume 63, pages 375 to 381 dated January 15, 2003	Exhibit 14 to the Deposition of Judy Lucas		PP
DTX-149	Deposition of James Gibbons	1	8/24/01 Wyeth Interoffice Correspondence	PFH-BOS01868771 - 780		
DTX-150	Deposition of James Gibbons	2	Article, Optimization of 4-Phenylamino 3-Quinolinecarbonitriles as Potent Inhibitors of Src Kinase Activity, the Journal of Medicinal Chemistry 2001	Exhibit 2 to the Deposition of James Gibbons	Tesconi Dep. Ex. 15; Feigelson Dep. Ex. 7; Lindsley Dep. Ex. 15; Murcko Resp Rep Ex E; D. Boschelli Dep. Ex. 38; Shah Validity Report Ex. MMM; Lindsley Reply Report Ex. B	PP
DTX-151	Deposition of James Gibbons	3	Email Correspondence, Subject:Manuscript Attached	PFE-BOS01772244		
DTX-152	Deposition of James Gibbons	5	Jennifer Golas et al., SKI-606, a 4-Anilino-3-quinolinecarbonitrile Dual Inhibitor of Src and Abl Kinases, Is a Potent Antiproliferative Agent Against Chronic Myelogenous Leukemia Cells in Culture and Causes Regression of K562 Xenografts in Nude Mice, 63 Cancer Res. 375, 376-77 (2003)	Exhibit 5 to the Deposition of James Gibbons	Levis Validity Report Ex. U; Lindsley Reply Report Ex. F; Shah Validity Report Ex. PPP	PP

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DTX-155	Deposition of Henry Strong	1	U.S. Patent 7,767,678 B2	EML015471		
DTX-156	Deposition of Henry Strong	2	Email from Tesconi to Clarke et al.	PFE-BOS01865456		
DTX-157	Deposition of Henry Strong	3	Meeting Minutes dated 6-25-03	PFE-BOS01532477 - 478		
DTX-158	Deposition of Henry Strong	4	Email from Ku to Hadfield and Strong	PFE-BOS02697233		
DTX-159	Deposition of Henry Strong	5	Confidential Laboratory Notebook L 23263	PFE-BOS02591297 - 509		
DTX-160	Deposition of Henry Strong	6	Confidential Laboratory Notebook L 27384	PFE-BOS02591593 - 804		
DTX-161	Deposition of Nicholas J. Donato	1	Notice of Subpoena	Exhibit 1 to the Deposition of Nicholas J. Donato		
DTX-162	Deposition of Nicholas J. Donato	2	Program of the American Society of Hematology - December 6-10, 2002	Exhibit 2 to the Deposition of Nicholas J. Donato		PP

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DTX-163	Deposition of Nicholas J. Donato	3	Article entitled BCR-ABL independence and LYN kinase overexpression in chronic myelogenous leukemia cells selected for resistance to STI-571	Exhibit 3 to the Deposition of Nicholas J. Donato		PP
DTX-164	Deposition of David Clarke	1	Defendants' Second Amended Notice of Deposition of Plaintiffs Pursuant to Federal Rule of Civil Procedure 30(b)(6)	Exhibit 1 to the Deposition of David Clarke		
DTX-165	Deposition of David Clarke	15	SKI-606 Oncology Global Development Team August 14, 2003 Meeting Minutes	PFE-BOS02605633 - 638		
DTX-166	Deposition of David Clarke	16	SKI-606 Oncology Global Development Team September 11, 2003 Meeting Minutes	PFE-BOS02689485 - 491		
DTX-167	Deposition of David Clarke	17	SKI-606 Oncology Global Development Team October 15, 2003 Meeting Minutes	PFE-BOS02694116 - 122		
DTX-168	Deposition of David Clarke	18	SKI-606 Oncology Global Development Team November 11, 2003 Meeting Minutes	PFE-BOS02694602 - 608		
DTX-169	Deposition of Rajeev S. Mathur	42	Statements of Certification Under Section 505(j)(2)(A)(vii) and 23 CFR 314.94(a)(12)	SUN-BOS0043563 - 568		

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DTX-170	Deposition of Rajeev S. Mathur	43	Strategic Note – Bosutinib Tablets 100 mg and 500 mg	SUN-BOS0082038 - 040		
DTX-171	Deposition of Rajeev S. Mathur	44	Regulatory Expectations	SUN-BOS0081749 - 753		
DTX-172	Deposition of Rajeev S. Mathur	45	FDA Complete Response Letter, dated October 29, 2018	SUN-BOS0089496 - 500		
DTX-173	Deposition of Rajeev S. Mathur	46	Cover Letter to Sun Pharmaceutical's Response to Complete Response Letter, dated February 1, 2019	SUN-BOS0089501 - 503		
DTX-174	Deposition of Rajeev S. Mathur	47	Sun Pharmaceutical's Response to Complete Response Letter, dated February 1, 2019	SUN-BOS0089504 - 506	Chyall Opening Report Ex. U	
DTX-175	Deposition of Rajeev S. Mathur	48	Sun's Annexure-1 XRD Overlay of Batch Nos. GKR0165B, GKR0164B, GKR0163B, GKR0162B, GKR0160B, GKR0161B, BS0031215, BS0010116, BS0021215, AMK(6680)011P (Placebo)	SUN-BOS0089448 - 493	Chyall Opening Report Ex. O	

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DTX-176	Deposition of Marc Sadler Tesconi	1	Defendant's Amended Notice of Deposition of Marc Sadler Tesconi	Exhibit 1 to the Deposition of Marc Sadler Tesconi		
DTX-177	Deposition of Marc Sadler Tesconi	2	Defendant's Third Amended Notice of Deposition of the Plaintiff Pursuant to Federal Rule of Civil Procedure 30(b)(6)	Exhibit 2 to the Deposition of Marc Sadler Tesconi		
DTX-178	Deposition of Marc Sadler Tesconi	6	Plaintiff's Supplemental Objections and Responses to Defendant's First Set of Joint Interrogatories	Exhibit 6 to the Deposition of Marc Sadler Tesconi		
DTX-179	Deposition of Marc Sadler Tesconi	7	Email attaching manuscript describing CML	PFE-BOS01772244 - 290		
DTX-180	Deposition of Marc Sadler Tesconi	9	Plaintiff's Second Supplemental Objections and Response to Defendant's Interrogatory No. 1	Exhibit 9 to the Deposition of Marc Sadler Tesconi		
DTX-181	Deposition of Marc Sadler Tesconi	10	Email re: Src Kinase WAY-173606	PFE-BOS 01754411		
DTX-182	Deposition of Marc Sadler Tesconi	12	Rationalization of the Formation and Stability of Bosutinib Solvated Forms	Exhibit 12 to the Deposition of Marc Sadler Tesconi		PP

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DTX-183	Deposition of Marc Sadler Tesconi	13	Confirmation of Bosutinib Structure; Demonstration of Controls to Ensure Product Quality	Exhibit 13 to the Deposition of Marc Sadler Tesconi		PP
DTX-184	Deposition of Marc Sadler Tesconi	16	Laboratory Notebook L23540	PFE-BOS02554109 - 321		
DTX-185	Deposition of Marc Sadler Tesconi	17	Laboratory Notebook L23541	PFE-BOS02554322 - 534		
DTX-186	Deposition of Marc Sadler Tesconi	18	Laboratory Notebook L24462	PFE-BOS02554831 - 5041		
DTX-187	Deposition of Marc Sadler Tesconi	19	Laboratory Notebook L24454	PFE-BOS02555042 - 253		
DTX-188	Deposition of Marc Sadler Tesconi	20	Laboratory Notebook L28411	PFE-BOS02591805 - 2018		
DTX-189	Deposition of Marc Sadler Tesconi	21	Laboratory Notebook L24711	PFE-BOS02594300 - 510		

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DTX-190	Deposition of Marc Sadler Tesconi	22	Meeting Minutes WAY 173606, Freebase Polymorph/Salt Selection	PFE-BOS01532477 - 478		
DTX-191	Deposition of Marc Sadler Tesconi	23	Technical Memo	PFE-BOS01850858 - 868		
DTX-200	Deposition of Marc Sadler Tesconi	33	Publication Presentation Approval Wyeth Research and Wyeth BioPharma	PFE-BOS02613006 - 007		
DTX-201	Deposition of Marc Sadler Tesconi	34	Publication Presentation Approval Wyeth-Ayerst Research	PFE-BOS02612930 - 931		
DTX-204	Deposition of Leonard J. Chyall	2	Exhibit AA of the Opening Expert Report of Leonard J. Chyall, PH.D. Regarding Infringement of U.S. Patent No. 7,767,678 by Sun Pharmaceutical Industries Limited and Sun Pharmaceutical Industries, Inc.	Excerpt from Exhibit 2 to the Deposition of Leonard J. Chyall		
DTX-208	Deposition of Bernhardt L. Trout, Ph.D.	3	Guide for the Care and Use of Laboratory Animals	Exhibit 3 to the Deposition of Bernhardt L. Trout, Ph. D.		PP

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DTX-222	Deposition of Craig W. Lindsley, Ph.D.	14	Curriculum vitae	Exhibit 14 to the Deposition of Craig W. Lindsley, Ph.D.		
DTX-223	Deposition of Craig W. Lindsley, Ph.D.	16	Article in Blood, Journal of the American Society of Hematology	Exhibit 16 to the Deposition of Craig W. Lindsley, Ph.D.		PP
DTX-224	Deposition of Craig W. Lindsley, Ph.D.	17	PCT patent application with international publication number WO03/013540 A1	Exhibit 17 to the Deposition of Craig W. Lindsley, Ph.D.		PP
DTX-256	Deposition of Piotr Karpinski, Ph.D.	7	U.S. Patent 8,343,984 B2	Exhibit 7 to the Deposition of Piotr Karpinski, Ph.D.		PP
DTX-257	Deposition of Piotr Karpinski, Ph.D.	8	U.S. Patent 7,989,494 B2	Exhibit 8 to the Deposition of Piotr Karpinski, Ph.D.		PP

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DTX-258	Deposition of Piotr Karpinski, Ph.D.	9	U.S. Patent 9,181,215 B2	Exhibit 9 to the Deposition of Piotr Karpinski, Ph.D.		PP
DTX-259	Deposition of Piotr Karpinski, Ph.D.	10	PCT Application, International Publication No. WO 2006/063762 A1	Exhibit 10 to the Deposition of Piotr Karpinski, Ph.D.		PP
DTX-260	Deposition of Piotr Karpinski, Ph.D.	11	U.S. Patent 8,486,930 B2	Exhibit 11 to the Deposition of Piotr Karpinski, Ph.D.		PP
DTX-261	Deposition of Piotr Karpinski, Ph.D.	12	Desiraju paper	Exhibit 12 to the Deposition of Piotr Karpinski, Ph.D.		PP
DTX-262	Deposition of Piotr Karpinski, Ph.D.	14	Bowles et al. Paper	Exhibit 14 to the Deposition of Piotr Karpinski, Ph.D.		PP

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DTX-268	Infringement Expert Report of Neil Shah	A	Certified U.S. Patent 7,417,148 B2	PFZFH000119 8 - 208	Lindsley Dep. Ex. 1; DTX-001; Shah Validity Report Ex. A; Levis Validity Report Ex. A; Murcko Responsive Report Ex. A	
DTX-269	Infringement Expert Report of Neil Shah	B	Certified U.S. Patent 7,919,625 B2	PFZFH000120 9 - 219	DTX-005; Lindsley Dep. Ex. 2; Shah Validity Report Ex. B; Trout Responsive Report Ex. A; Murcko Responsive Report Ex. A; Levis Validity Report Ex. B	
DTX-270	Infringement Expert Report of Neil Shah	C	Curriculum vitae of Neil Pravin Shah	Exhibit C to the Infringement Expert Report of Neil Shah	Shah Validity Report Ex. C	
DTX-271	Infringement Expert Report of Neil Shah	D	Mercedes E. Gorre et al., Clinical Resistance to STI-571 Cancer Therapy Caused by BCR-ABL Gene Mutation or Amplification, 293 Science 876 (2001)	Exhibit D to the Infringement Expert Report of Neil Shah	Shah Validity Report Ex. D; Murcko Responsive Report Ex. KK	PP

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DTX-272	Infringement Expert Report of Neil Shah	E	Neil P. Shah et al., Multiple BCR-ABL Kinase Domain Mutations Confer Polyclonal Resistance to the Tyrosine Kinase Inhibitor Imatinib (STI571) in Chronic Phase and Blast Crisis Chronic Myeloid Leukemia, 2 CANCER CELL 117 (2002)	Exhibit E to the Infringement Expert Report of Neil Shah	Validity Expert Report of Neil Shah Ex. E	PP
DTX-273	Infringement Expert Report of Neil Shah	F	Neil P. Shah et al., Overriding Imatinib Resistance with a Novel ABL Kinase Inhibitor, 305 SCIENCE 399 (2004)	Exhibit F to the Infringement Expert Report of Neil Shah	Validity Expert Report of Neil Shah Ex. F	PP
DTX-274	Infringement Expert Report of Neil Shah	G	Moshe Talpaz et al., Dasatinib in Imatinib-Resistant Philadelphia Chromosome-Positive Leukemias, 354 N. Eng. J. Med. 2531 (2006)	Exhibit G to the Infringement Expert Report of Neil Shah	Shah Validity Report Ex. G; Lindsley Reply Report Ex. L	PP
DTX-275	Infringement Expert Report of Neil Shah	H	Neil P. Shah et al., Intermittent Target Inhibition With Dasatinib 100 mg Once Daily Preserves Efficacy and Improves Tolerability in Imatinib-Resistant and -Intolerant Chronic-Phase Chronic Myeloid Leukemia, 26 J. CLINICAL ONCOLOGY 3204 (2008)	Exhibit H to the Infringement Expert Report of Neil Shah	Validity Expert Report of Neil Shah Ex. H	PP

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DTX-276	Infringement Expert Report of Neil Shah	I	Hagop Kantarjian et al., Dasatinib versus Imatinib in Newly Diagnosed Chronic-Phase Chronic Myeloid Leukemia, 362 N. Eng. J. Med. 2260 (2010)	Exhibit I to the Infringement Expert Report of Neil Shah	Shah Validity Report Ex. I	PP
DTX-277	Infringement Expert Report of Neil Shah	J	Jorge E. Cortes et al., Ponatinib in Refractory Philadelphia Chromosome–Positive Leukemias, 367 N. Eng. J. Med. 2075 (2012)	Exhibit J to the Infringement Expert Report of Neil Shah	Shah Validity Report Ex. J	PP
DTX-278	Infringement Expert Report of Neil Shah	K	Jorge E. Cortes et al., A Phase 2 Trial of Ponatinib in Philadelphia Chromosome–Positive Leukemias, 369 N. Eng. J. Med. 1783 (2013)	Exhibit K to the Infringement Expert Report of Neil Shah	Shah Validity Report Ex. K	PP
DTX-279	Infringement Expert Report of Neil Shah	L	Neil P. Shah et al., Long-Term Outcome with Dasatinib After Imatinib Failure in Chronic-Phase Chronic Myeloid Leukemia: Follow-up of a Phase 3 Study, 123 BLOOD 2317 (2014)	Exhibit L to the Infringement Expert Report of Neil Shah	Validity Expert Report of Neil Shah Ex. L	PP

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DTX-280	Infringement Expert Report of Neil Shah	M	Jennifer Asmussen et al., MEK-Dependent Negative Feedback Underlies BCR-ABL-Mediated Oncogene Addiction, 73 CANCER DISCOVERY 200 (2014)	Exhibit M to the Infringement Expert Report of Neil Shah	Validity Expert Report of Neil Shah Ex. M	PP
DTX-281	Infringement Expert Report of Neil Shah	N	Srdan Verstovsek et al., Phase I Evaluation of XL019, an Oral, Potent, and Selective JAK2 Inhibitor, 38 LEUKEMIA RES. 316 (2014)	Exhibit N to the Infringement Expert Report of Neil Shah	Validity Expert Report of Neil Shah Ex. N	PP
DTX-282	Infringement Expert Report of Neil Shah	O	Catherine C. Smith et al., Crenolanib is a Selective Type I pan-FLT3 Inhibitor, 111 Proc. Nat'l Acad. Sci. 5319 (2014)	Exhibit O to the Infringement Expert Report of Neil Shah	Validity Expert Report of Neil Shah Ex. O	PP
DTX-283	Infringement Expert Report of Neil Shah	P	Joint Claim Construction Brief, Dkt. 91	Exhibit P to the Infringement Expert Report of Neil Shah	Validity Expert Report of Neil Shah Ex. P; Murcko Responsive Report Ex. F; Trout Responsive Report Ex. D; Levis Validity Report Ex. D	U

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DTX-284	Infringement Expert Report of Neil Shah	Q	List of materials considered	Exhibit Q to the Infringement Expert Report of Neil Shah	Validity Expert Report of Neil Shah Ex. Q	
DTX-285	Infringement Expert Report of Neil Shah	R	Peter C. Nowell, Discovery of the Philadelphia Chromosome: a Personal Perspective, 117 J. CLINICAL INVESTIGATION 2033 (2007)	Exhibit R to the Infringement Expert Report of Neil Shah	Validity Expert Report of Neil Shah Ex. R; Levis Validity Report Ex. G	PP
DTX-286	Infringement Expert Report of Neil Shah	S	James B. Konopka et al., An Alteration of the Human c-abl Protein in K562 Leukemia Cells Unmasks Associated Tyrosine Kinase Activity, 37 CELL 1035 (1984)	Exhibit S to the Infringement Expert Report of Neil Shah	Shah Validity Report Ex. BB; Levis Validity Report Ex. H	PP
DTX-287	Infringement Expert Report of Neil Shah	T	Nora Heisterkamp et al., Structural Organization of the bcr Gene and its Role in the Ph' Translocation, 315 Nature 758 (1985)	Exhibit T to the Infringement Expert Report of Neil Shah	Shah Validity Report Ex. DD; Levis Validity Report Ex. I	PP

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DTX-288	Infringement Expert Report of Neil Shah	U	Merat K. Esfahani et al., Blastic Phase of Chronic Myelogenous Leukemia, 7 Current Treatment Options in Oncology 189 (2006)	Exhibit U to the Infringement Expert Report of Neil Shah	Shah Validity Report Ex. S; Levis Validity Report Ex. J	PP
DTX-289	Infringement Expert Report of Neil Shah	V	Rüdiger Hehlmann et al., Management of CML-Blast Crisis, 29 BEST PRAC. & RES. CLINICAL HAEMATOLOGY 295, 300-01 (2016)	Exhibit V to the Infringement Expert Report of Neil Shah	Shah Validity Report Ex. T	PP
DTX-290	Infringement Expert Report of Neil Shah	W	Nikolas von Bubnoff et al., Bcr-Abl Gene Mutations in Relation to Clinical Resistance of Philadelphia-Chromosome-Positive Leukaemia to STI571: a Prospective Study, 359 LANCET 487 (2002)	Exhibit W to the Infringement Expert Report of Neil Shah	Shah Validity Report Ex. BBB	PP
DTX-291	Infringement Expert Report of Neil Shah	X	BOSULIF®(bosuthilb) tablets, for oral use, Initial U.S. Approval: 2012	PFE-BOS02522143 - 166	Thirman Reply Report Ex. L; Shah Validity Report Ex. FFFF; Levis Validity Report Ex. FF	
DTX-312	Validity Expert Report of Neil Shah	Q	List of materials considered	Exhibit Q to the Validity Expert Report of Neil Shah	Infringement Expert Report of Neil Shah Ex. Q	

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DTX-317	Validity Expert Report of Neil Shah	V	Robert D. Lange et al., Leukemia in Atomic Bomb Survivors: I. General Observations, 9 BLOOD 574, 582 (1954)	Exhibit V to the Validity Expert Report of Neil Shah		PP
DTX-318	Validity Expert Report of Neil Shah	W	Janet D. Rowley, Letter: A New Consistent Chromosomal Abnormality in Chronic Myelogenous Leukaemia Identified by Quinacrine Fluorescence and Giemsa Staining, 243 NATURE 290, 291 (1973)	Exhibit W to the Validity Expert Report of Neil Shah		PP
DTX-319	Validity Expert Report of Neil Shah	X	Mamta Kalidas et al., Chronic Myelogenous Leukemia, 286 J. AM. MED. ASS'N 895 (2001)	Exhibit X to the Validity Expert Report of Neil Shah	Lindsley Dep. Ex. 27	PP
DTX-320	Validity Expert Report of Neil Shah	Y	Owen N. Witte et al., Abelson Murine Leukaemia Virus Protein is Phosphorylated in vitro to Form Phosphotyrosine, 283 NATURE 826 (1980)	Exhibit Y to the Validity Expert Report of Neil Shah		PP

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DTX-322	Validity Expert Report of Neil Shah	AA	Nora Heisterkamp et al., Localization of the c-abl Oncogene Adjacent to a Translocation Break Point in Chronic Myelocytic Leukaemia, 306 NATURE 239 (1983)	Exhibit AA to the Validity Expert Report of Neil Shah		PP
DTX-324	Validity Expert Report of Neil Shah	CC	Emma Shtivelman, Fused Transcript of abl and bcr Genes in Chronic Myelogenous Leukaemia, 315 NATURE 550 (1985)	Exhibit CC to the Validity Expert Report of Neil Shah		PP
DTX-326	Validity Expert Report of Neil Shah	EE	Tracy G. Lugo et al., Tyrosine Kinase Activity and Transformation Potency of bcr-abl Oncogene Products, 247 SCIENCE 1079 (1990)	Exhibit EE to the Validity Expert Report of Neil Shah		PP
DTX-327	Validity Expert Report of Neil Shah	FF	George Q. Daley et al., Induction of Chronic Myelogenous Leukemia in Mice by the P210bcr/abl Gene of the Philadelphia Chromosome, 247 SCIENCE 824 (1990)	Exhibit FF to the Validity Expert Report of Neil Shah		PP

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DTX-329	Validity Expert Report of Neil Shah	HH	Xiaowu Zhang & Ruibao Ren, Bcr-Abl Efficiently Induces a Myeloproliferative Disease and Production of Excess Interleukin-3 and Granulocyte-Macrophage Colony-Stimulating Factor in Mice: A Novel Model for Chronic Myelogenous Leukemia, 92 BLOOD 3829 (1998)	Exhibit HH to the Validity Expert Report of Neil Shah		PP
DTX-331	Validity Expert Report of Neil Shah	JJ	Junko Sonoyama et al., Functional Cooperation Among Ras, STAT5, and Phosphatidylinositol 3-Kinase Is Required for Full Oncogenic Activities of BCR/ABL in K562 Cells, 277 J. BIOLOGICAL CHEMISTRY 8076 (2002)	Exhibit JJ to the Validity Expert Report of Neil Shah		PP
DTX-332	Validity Expert Report of Neil Shah	KK	Ruibao Ren, Dissecting the Molecular Mechanism of Chronic Myelogenous Leukemia Using Murine Models, 43 LEUKEMIA & LYMPHOMA 1549 (2002)	Exhibit KK to the Validity Expert Report of Neil Shah		PP
DTX-333	Validity Expert Report of Neil Shah	LL	Peyton Rous, A Transmissible Avian Neoplasm: Sarcoma of the Common Fowl, 12 J. EXPERIMENTAL MED. 696 (1910)	Exhibit LL to the Validity Expert Report of Neil Shah		PP

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DTX-334	Validity Expert Report of Neil Shah	MM	Dominique Stehelin et al., Detection and Enumeration of Transformation-Defective Strains of Avian Sarcoma Virus with Molecular Hybridization, 76 VIROLOGY 675 (1977)	Exhibit MM to the Validity Expert Report of Neil Shah		PP
DTX-335	Validity Expert Report of Neil Shah	NN	Hermann Oppermann et al., Uninfected Vertebrate Cells Contain a Protein that is Closely Related to the Product of the Avian Sarcoma Virus Transforming Gene (Src), 76 PROC. NAT'L ACAD. SCI. 1804 (1979)	Exhibit NN to the Validity Expert Report of Neil Shah		PP
DTX-336	Validity Expert Report of Neil Shah	OO	Nobel Media AG, The Nobel Prize in Physiology or Medicine 1989, THE NOBEL FOUNDATION (1989), https://www.nobelprize.org/prizes/medicine/1989/summary/	Exhibit OO to the Validity Expert Report of Neil Shah		PP
DTX-337	Validity Expert Report of Neil Shah	PP	Tony Hunter & Bartholomew M. Sefton, Transforming Gene Product of Rous Sarcoma Virus Phosphorylates Tyrosine, 77 PROC. NAT'L ACAD. SCI. 1311, 1311, 1313 (1980)	Exhibit PP to the Validity Expert Report of Neil Shah		PP
DTX-338	Validity Expert Report of Neil Shah	QQ	Rosalyn B. Irby et al., Activating SRC Mutation in a Subset of Advanced Human Colon Cancers, 21 NATURE Genetics 187 (1999)	Exhibit QQ to the Validity Expert Report of Neil Shah		PP
DTX-340	Validity Expert Report of Neil Shah	SS	Dan R. Robinson et al., The Protein Tyrosine Kinase Family of the Human Genome, 19 ONCOGENE 5548 (2000)	Exhibit SS to the Validity Expert Report of Neil Shah		PP

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DTX-344	Validity Expert Report of Neil Shah	WW	Jack M. Lionberger et al., Transformation of Myeloid Leukemia Cells to Cytokine Independence by Bcr-Abl is Suppressed by Kinase-Defective Hck, 275 J. BIOLOGICAL CHEMISTRY 18581, 18581-82 (2000)	Exhibit WW to the Validity Expert Report of Neil Shah	Lindsley Dep. Ex. 25; Lindsley Reply Report Ex. H	PP
DTX-353	Validity Expert Report of Neil Shah	GGG	Robert L. Panek et al., In Vitro Pharmacological Characterization of PD 166285, a New Nanomolar Potent and Broadly Active Protein Tyrosine Kinase Inhibitor, 283 J. PHARMACOLOGY AND EXPERIMENTAL THERAPEUTICS 1433 (1997)	Exhibit GGG to the Validity Expert Report of Neil Shah		PP
DTX-354	Validity Expert Report of Neil Shah	HHH	V. Roginskaya et al., Therapeutic Targeting of Src-Kinase Lyn in Myeloid Leukemic Cell Growth, 13 LEUKEMIA 855 (1999)	Exhibit HHH to the Validity Expert Report of Neil Shah	Lindsley Dep. Ex. 20	PP
DTX-356	Validity Expert Report of Neil Shah	JJJ	Alan J. Kraker, Biochemical and Cellular Effects of c-Src Kinase-Selective Pyrido[2,3-d]pyrimidine Tyrosine Kinase Inhibitors, 60 BIOCHEMICAL PHARMACOLOGY 885, 888 (2000)	Exhibit JJJ to the Validity Expert Report of Neil Shah		PP

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DTX-360	Validity Expert Report of Neil Shah	NNN	Frank Boschelli et al., Dual Src/Abl Kinase Inhibitor Causes Regression of CML Xenografts in Nude Mice, 100 BLOOD 786a (2002)	Exhibit NNN to the Validity Expert Report of Neil Shah	Lindsley Reply Report Ex. C	PP
DTX-361	Validity Expert Report of Neil Shah	OOO	Nicholas J. Donato et al., Novel Tyrosine Kinase Inhibitors Suppress BCR-ABL Signaling and Induce Apoptosis in STI-571 Sensitive and Resistant CML Cells, 100 BLOOD 370a (2002)	Exhibit OOO to the Validity Expert Report of Neil Shah		PP
DTX-363	Validity Expert Report of Neil Shah	RRR	Nan Zhang et al., Synthesis and Structure-Activity Relationships of 3-Cyano-4-(phenoxyanilino)quinolines as MEK (MAPKK) Inhibitors, 10 BIOORGANIC & MED. CHEMISTRY LETTERS 2825 (2000)	Exhibit RRR to the Validity Expert Report of Neil Shah	Lindsley Dep. Ex. 26	PP

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DTX-368	Validity Expert Report of Neil Shah	WWW	Brigette Ma et al., Clinical trial designs for targeted agents, 16 HEMATOLOGY ONCOLOGY CLINICS N. AM. 1287 (2002)	Exhibit WWW to the Validity Expert Report of Neil Shah	Lindsley Dep. Ex. 36	PP
DTX-370	Validity Expert Report of Neil Shah	YYY	WO 03/013540	Exhibit YYY to the Validity Expert Report of Neil Shah		PP
DTX-371	Validity Expert Report of Neil Shah	ZZZ	Xuemei Sun et al., Comparison of Effects of the Tyrosine Kinase Inhibitors AG957, AG490, and STI571 on BCR-ABL–Expressing Cells, Demonstrating Synergy Between AG490 and STI571, 97 BLOOD 2008 (2001)	Exhibit ZZZ to the Validity Expert Report of Neil Shah		PP
DTX-372	Validity Expert Report of Neil Shah	AAAA	M. Stanglmaier et al., The Interaction of the Bcr-Abl Tyrosine Kinase with the Src Kinase Hck Is Mediated by Multiple Binding Domains, 17 LEUKEMIA 283 (2003)	Exhibit AAAA to the Validity Expert Report of Neil Shah		PP

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DTX-373	Validity Expert Report of Neil Shah	BBBB	Louise Tatton et al., The Src-selective Kinase Inhibitor PP1 Also Inhibits Kit and Bcr-Abl Tyrosine Kinases, 278 J. BIOLOGICAL CHEMISTRY 4847 (2003)	Exhibit BBBB to the Validity Expert Report of Neil Shah	Lindsley Reply Report Ex. N	PP
DTX-374	Validity Expert Report of Neil Shah	CCCC	Dan Berger et al., Synthesis and Evaluation of 4-Anilino-6,7-dialkoxy-3-quinolinecarbonitriles as Inhibitors of Kinases of the Ras-MAPK Signaling Cascade, 13 BIOORGANIC & MED. CHEMISTRY LETTERS 3031 (2003)	Exhibit CCCC to the Validity Expert Report of Neil Shah		PP
DTX-375	Validity Expert Report of Neil Shah	DDDD	David Cortez et al., Structural and Signaling Requirements for BCR-ABL-Mediated Transformation and Inhibition of Apoptosis, 15 MOLECULAR & CELLULAR BIOLOGY 5531 (1995)	Exhibit DDDD to the Validity Expert Report of Neil Shah		PP
DTX-376	Validity Expert Report of Neil Shah	EEEE	Shingo Dan et al., Selective Induction of Apoptosis in Philadelphia Chromosome-Positive Chronic Myelogenous Leukemia Cells by an Inhibitor of BCR-ABL Tyrosine Kinase, CGP 57148, 5 CELL DEATH & DIFFERENTIATION 710, 712 (1998)	Exhibit EEEE to the Validity Expert Report of Neil Shah		PP

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DTX-380	Validity Expert Report of Neil Shah	IIII	U.S. PTO Provisional Application 60/311,690	Exhibit IIII to the Validity Expert Report of Neil Shah		PP
DTX-381	Infringement Reply Expert Report of Dr. Neil Shah	DD	Gleevec (imatinib mesylate) Labeling	Exhibit DD to the Infringement Reply Expert Report of Dr. Neil Shah		
DTX-384	Infringement Reply Expert Report of Dr. Neil Shah	GG	Jorge E. Cortes et al., Bosutinib Versus Imatinib in Newly Diagnosed Chronic-Phase Chronic Myeloid Leukemia: Results From the BELA Trial, 30 J. Clinical Oncology 3846 (2012)	Exhibit GG to the Infringement Reply Expert Report of Dr. Neil Shah		PP

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DTX-388	Opening Report of Craig W. Lindsley	B	Curriculum vitae of Dr. Craig Lindsley	Exhibit B to the Opening Report of Craig W. Lindsley		
DTX-389	Opening Report of Craig W. Lindsley	C	Dan Berger et al., Synthesis and Evaluation of 4-Anilino-6,7-dialkoxy-3-quinolinecarbonitriles as Inhibitors of Kinases of the Ras-MAPK Signaling Cascade, 13 BIOORGANIC & MED. CHEMISTRY LETTERS 3031 (2003)	SUN-BOS0011827 - 830		PP

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DTX-416	Opening Report of Craig W. Lindsley	DD	Louise Tatton et al., The Src-selective Kinase Inhibitor PP1 Also Inhibits Kit and Bcr-Abl Tyrosine Kinases, 278 J. BIOLOGICAL CHEMISTRY 4847 (2003)	SUN-BOS0012268 - 275		PP
DTX-417	Opening Report of Craig W. Lindsley	EE	Warmuth et al., The Src Family Kinase Hck Interacts with Bcr-Abl by a Kinase-Independent Mechanism and Phosphorylates the Grb2-Binding Site of Bcr, J. Biol. Chem. 272(52):33260-33270 (1997)	SUN-BOS0012434 - 445		PP
DTX-418	Opening Report of Craig W. Lindsley	FF	Warmuth et al., Dual-Specific Src and Abl Kinase Inhibitors, PP1 and CGP76030, Inhibit Growth and Survival of Cells Expressing Imatinib Mesylate-Resistant Bcr-Abl Kinases, Blood 101:664-672 (2003)	SUN-BOS0012446 - 454		PP
DTX-419	Opening Report of Craig W. Lindsley	GG	Matthew B. Wilson et al., Selective Pyrrolo-pyrimidine Inhibitors Reveal a Necessary Role for Src Family Kinases in Bcr-Abl Signal Transduction and Oncogenesis, 21 Oncogene 8075 (2002)	SUN-BOS0012455 - 468		PP
DTX-420	Opening Report of Craig W. Lindsley	HH	David Wisniewski et al., Characterization of Potent Inhibitors of the Bcr-Abl and the c-Kit Receptor Tyrosine Kinases, 62 Cancer Research 4244 (2002)	SUN-BOS0090332 - 344		PP

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DTX-421	Opening Report of Craig W. Lindsley	II	Nan Zhang et al., Synthesis and Structure-Activity Relationships of 3-Cyano-4-(phenoxyanilino)quinolines as MEK (MAPKK) Inhibitors, 10 BIOORGANIC & MED. CHEMISTRY LETTERS 2825 (2000)	SUN-BOS0090345 - 348		PP
DTX-422	Reply Expert Report of Craig W. Lindsley	A	List of Materials Considered	Exhibit A to the Reply Expert Report of Craig W. Lindsley		
DTX-428	Reply Expert Report of Craig W. Lindsley	G	Kantarjian et al., Nilotinib in imatinib-resistant CML and Philadelphia chromosome-positive ALL, New Engl J Med 354(24):2542-51 (2006)	Exhibit G to the Reply Expert Report of Craig W. Lindsley		PP
DTX-431	Reply Expert Report of Craig W. Lindsley	J	Norman, Drugs, Devices, and the FDA: Part 1: An Overview of Approval Processes for Drugs, JACC : Basic To Translational Science Vol. 1, No. 3, 170-179 (2016)	Exhibit J to the Reply Expert Report of Craig W. Lindsley	Thirman Reply Report Ex. K	PP
DTX-432	Reply Expert Report of Craig W. Lindsley	K	SPRYCEL Prescribing Information, available at http://packageinserts.bms.com/pi/pi_spry cel.pdf	Exhibit K to the Reply Expert Report of Craig W. Lindsley		

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DTX-434	Reply Expert Report of Craig W. Lindsley	M	TASIGNA Prescribing Information, available at https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/tasigna.pdf	Exhibit M to the Reply Expert Report of Craig W. Lindsley		
DTX-438	Reply Expert Report of Craig W. Lindsley	Q	Williams, et al., Insights into Src kinase functions: structural comparisons, Trends in Biochemical Sciences, 23(5):179-184 (1998)	Exhibit Q to the Reply Expert Report of Craig W. Lindsley		PP
DTX-443	Opening Expert Report of Leonard Chyall	B	Curriculum Vitae of Leonard J. Chyall, Ph.D.	Exhibit B to the Opening Expert Report of Leonard Chyall		
DTX-444	Opening Expert Report of Leonard Chyall	C	Chyall Materials Considered	Exhibit C to the Opening Expert Report of Leonard Chyall		

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DTX-445	Opening Expert Report of Leonard Chyall	D	Markman Order, D.I. 98	Exhibit D to the Opening Expert Report of Leonard Chyall	Chyal Validity Report Ex. AA; Validity Expert Report of Mark Levis Ex. E; Responsive Expert Report of Berhardt L. Trout Ex. E; Murcko Responsive Report Ex. MM	U
DTX-446	Opening Expert Report of Leonard Chyall	E	William Clegg, Crystal Structure Determination 1-21 (John Evans ed., 1998)	Exhibit E to the Opening Expert Report of Leonard Chyall	Chyall Validity Report Ex. D	PP
DTX-447	Opening Expert Report of Leonard Chyall	F	John K. Haleblan, Characterization of Habits and Crystalline Modification of Solids and Their Pharmaceutical Applications, 64 J. Pharm. Sci. 1269 (1975)	Exhibit F to the Opening Expert Report of Leonard Chyall	Chyall Validity Report Ex. E	PP
DTX-448	Opening Expert Report of Leonard Chyall	G	Igor Ivanisevic et al., Uses of X-Ray Powder Diffraction In the Pharmaceutical Industry (Shayne C. Gad ed., 2010)	Exhibit G to the Opening Expert Report of Leonard Chyall	Chyall Validity Report Ex. H	PP

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DTX-449	Opening Expert Report of Leonard Chyall	H	Steve J. Chipera & David L. Bish, Fitting Full X-Ray Diffraction Patterns for Quantitative Analysis: A Method for Readily Quantifying Crystalline and Disordered Phases, 3 Advances in Materials Physics and Chemistry 47 (2013)	Exhibit H to the Opening Expert Report of Leonard Chyall		PP
DTX-450	Opening Expert Report of Leonard Chyall	I	G.S. Pawley, Unit-cell Refinement From Powder Diffraction Scans, 14 J. Applied Crystallography 357 (1981)	Exhibit I to the Opening Expert Report of Leonard Chyall		PP
DTX-451	Opening Expert Report of Leonard Chyall	J	U.S. Pharmacopeia 27, Ch. 891, Thermal Analysis (27th rev. 2004)	Exhibit J to the Opening Expert Report of Leonard Chyall	Chyall Validity Report Ex. K	PP
DTX-452	Opening Expert Report of Leonard Chyall	K	Harry G. Brittain, Methods for the Characterization of Polymorphs and Solvates, in 95 Drugs and the Pharmaceutical Sciences, Polymorphism in Pharmaceutical Solids 227 (James Swarbrick ed., 1999)	Exhibit K to the Opening Expert Report of Leonard Chyall	Chyall Validity Report Ex. L	PP
DTX-453	Opening Expert Report of Leonard Chyall	L	Eszter Tieger et al., Rationalization of the Formation and Stability of Bosutinib Solvated Forms, 18 CrystEngComm. 9260 (2016)	Exhibit L to the Opening Expert Report of Leonard Chyall		PP

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DTX-465	Opening Expert Report of Leonard Chyall	X	Overlay plot of the XRPD pattern provided in Fig. 1, Pattern A of US Patent No. 7,767,678 with the XRPD pattern for 100 mg Sun's ANDA Product Batch No. GKR0162B obtained by SSCI	Exhibit X to the Opening Expert Report of Leonard Chyall		
DTX-466	Opening Expert Report of Leonard Chyall	Y	Overlay plot of the XRPD pattern provided in Fig. 1, Pattern A of US Patent No. 7,767,678 with the XRPD pattern for 500 mg Sun's ANDA Product Batch No. GKR0165B obtained by SSCI	Exhibit Y to the Opening Expert Report of Leonard Chyall		
DTX-467	Opening Expert Report of Leonard Chyall	Z	Report of Richard B. McClurg, Ph.D., titled "Characterization of Sun Pharmaceutical Bosutinib Products"	Exhibit Z to the Opening Expert Report of Leonard Chyall		
DTX-468	Opening Expert Report of Leonard Chyall	AA	Overlay plot of the XRPD pattern provided in Fig. 1, Pattern A of US Patent No. 7,767,678 with the XRPD pattern for Pfizer's sample of Form I bosutinib API obtained by SSCI	Exhibit AA to the Opening Expert Report of Leonard Chyall		
DTX-469	Opening Expert Report of Leonard Chyall	BB	Sun list of each and every recited peak in claim 2 of the '678 patent in its analysis of the XRPD patterns generated by Sun of samples of Sun's ANDA Products	SUN-BOS0024881 - 882		

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DTX-470	Opening Expert Report of Leonard Chyall	CC	Sun list of each and every recited peak in claim 2 of the '678 patent in its analysis of the XRPD patterns generated by Sun of samples of Sun's ANDA Products	SUN-BOS0024861		
DTX-471	Opening Expert Report of Leonard Chyall	DD	Overlay plot of the XRPD pattern provided in Fig. 1, Pattern A of US Patent No. 7,767,678 with the XRPD pattern for 100 mg Sun's ANDA Product Batch No. GKR0162B as shown on SUN-BOS0024879	SUN-BOS0024879		
DTX-472	Opening Expert Report of Leonard Chyall	EE	Overlay plot of the XRPD pattern provided in Fig. 1, Pattern A of US Patent No. 7,767,678 with the XRPD pattern for 500 mg Sun's ANDA Product Batch No. GKR0165B as shown on SUN-BOS0024859	SUN-BOS0024859		
DTX-473	Opening Expert Report of Leonard Chyall	FF	Overlay plot of the XRPD pattern provided in Fig. 1, Pattern A of US Patent No. 7,767,678 with the XRPD pattern for 100 mg Sun's ANDA Product Batch No. GKR0162B as shown on SUN-BOS0089455	SUN-BOS0089455		
DTX-474	Opening Expert Report of Leonard Chyall	GG	Overlay plot of the XRPD pattern provided in Fig. 1, Pattern A of US Patent No. 7,767,678 with the XRPD pattern for 500 mg Sun's ANDA Product Batch No. GKR0165B as shown on SUN-BOS0089449	SUN-BOS0089449		

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DTX-476	Validity Expert Report of Leonard J. Chyall	B	Curriculum vitae of Dr. Leonard Chyall	Exhibit B to the Validity Expert Report of Leonard J. Chyall		
DTX-477	Validity Expert Report of Leonard J. Chyall	C	List of materials relied upon	Exhibit C to the Validity Expert Report of Leonard J. Chyall		
DTX-480	Validity Expert Report of Leonard J. Chyall	F	Joel Bernstein, Polymorphism in Molecular Crystals, at 2-8 (2002)	Exhibit F to the Validity Expert Report of Leonard J. Chyall		PP
DTX-481	Validity Expert Report of Leonard J. Chyall	G	Bernstein at 111-125; United States Pharmacopeia, USP 28, NF 23, Ch. 941 X-Ray (Jan. 1, 2005)	Exhibit G to the Validity Expert Report of Leonard J. Chyall		PP
DTX-483	Validity Expert Report of Leonard J. Chyall	I	United States Pharmacopeia, USP 25, NF 20, Chapter 741 Melting Point (Jan. 1, 2002)	Exhibit I to the Validity Expert Report of Leonard J. Chyall		PP

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DTX-484	Validity Expert Report of Leonard J. Chyall	J	Royston M. Roberts et al., Chapter 3: Solids: Recrystallization and Melting Points, in MODERN EXPERIMENTAL ORGANIC CHEMISTRY, at 81 (1985)	Exhibit J to the Validity Expert Report of Leonard J. Chyall		PP
DTX-486	Validity Expert Report of Leonard J. Chyall	O	Eun Hee Lee, A Practical Guide to Pharmaceutical Polymorph Screening & Selection, 9 Asian J. Pharm. Sci. 163, 169 (2014)	Exhibit O to the Validity Expert Report of Leonard J. Chyall		PP
DTX-487	Validity Expert Report of Leonard J. Chyall	R	International Patent Publication, WO 2003/093241	Exhibit R to the Validity Expert Report of Leonard J. Chyall		PP
DTX-488	Validity Expert Report of Leonard J. Chyall	S	European Medicines Agency, ICH Harmonised Tripartite Guideline, "Topic Q6A. Specifications, Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances" (2000)	SUN-BOS0012065 - 096		PP
DTX-489	Validity Expert Report of Leonard J. Chyall	T	European Medicines Agency, Committee for Proprietary Medicinal Products (CPMP) "Guideline on the Chemistry of New Active Substances" (2003)	SUN-BOS0012052 - 064		PP

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DTX-490	Validity Expert Report of Leonard J. Chyall	V	Raw et al., Regulatory Considerations of Pharmaceutical Solid Polymorphism in Abbreviated New Drug Applications, 56 Adv. Drug. Deliv. Rev. 397 (2004)	Exhibit V to the Validity Expert Report of Leonard J. Chyall		PP
DTX-491	Validity Expert Report of Leonard J. Chyall	W	Threlfall, "Analysis of Organic Polymorphs, A Review," 120 Analyst 2435 (1995)	Exhibit W to the Validity Expert Report of Leonard J. Chyall		PP
DTX-492	Validity Expert Report of Leonard J. Chyall	Y	"International Conference on Harmonisation; Guidance on Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances," 65 Federal Register 83041-63 (2000)	Exhibit Y to the Validity Expert Report of Leonard J. Chyall		PP
DTX-494	Validity Expert Report of Leonard J. Chyall	BB	Richard W. Ramette, CHEMICAL EQUILIBRIUM AND ANALYSIS at 49-64 (1981)	Exhibit BB to the Validity Expert Report of Leonard J. Chyall		PP
DTX-495	Validity Expert Report of Leonard J. Chyall	CC	John R. Taylor, AN INTRODUCTION TO ERROR ANALYSIS: THE STUDY OF UNCERTAINTIES IN PHYSICAL MEASUREMENTS, at 3-24 (2d ed. 1997)	Exhibit CC to the Validity Expert Report of Leonard J. Chyall		PP

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DTX-496	Validity Expert Report of Leonard J. Chyall	DD	Sampath S. Iyengar et al., Quantitative Analyses of Complex Pharmaceutical Mixtures by the Rietveld Method, 16(1) Powder Diffraction 20, 23 (March 2001)	Exhibit DD to the Validity Expert Report of Leonard J. Chyall		PP
DTX-497	Validity Expert Report of Leonard J. Chyall	FF	Gregory Stephenson et al., Characterization of the Solid State: Quantitative Issues, 48 Advanced Drug Delivery Reviews 67, 87 (2001)	Exhibit FF to the Validity Expert Report of Leonard J. Chyall		PP
DTX-498	Validity Expert Report of Leonard J. Chyall	II	Qiu, J. et al., Quantification of febuxostat polymorphs using powder X-ray diffraction technique, 107 J. Pharm. and Biomed. Analysis, 298, 302 (2015)	Exhibit II to the Validity Expert Report of Leonard J. Chyall		PP
DTX-499	Validity Expert Report of Leonard J. Chyall	OO	Piqi Zhao et al., Error Analysis and Correction for Quantitative Phase Analysis Based on Rietveld-Internal Standard Method: Whether the Minor Phases Can Be Ignored?, 8 Crystals 110, at 3 (of 11) (2018)	Exhibit OO to the Validity Expert Report of Leonard J. Chyall		PP
DTX-500	Validity Expert Report of Leonard J. Chyall	PP	De la Torre, A.G.; Bruque, S.; Aranda, M.A.G. Rietveld Quantitative Amorphous Content Analysis, 34 J. Appl. Crystallogr. 196 (2001)	Exhibit PP to the Invalidity expert report of Leonard J. Clark		PP

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DTX-501	Validity Expert Report of Leonard J. Chyall	QQ	WO 2011/161245	Exhibit QQ to the Validity Expert Report of Leonard J. Chyall		PP
DTX-502	Validity Expert Report of Leonard J. Chyall	RR	U.S. Patent 7,345,171 B2	Exhibit RR to the Validity Expert Report of Leonard J. Chyall		PP
DTX-503	Validity Expert Report of Leonard J. Chyall	SS	U.S. Patent 7,977,357 B2	Exhibit SS to the Validity Expert Report of Leonard J. Chyall		PP
DTX-504	Validity Expert Report of Leonard J. Chyall	TT	U.S. Patent 5,118,483	Exhibit TT to the Validity Expert Report of Leonard J. Chyall		PP
DTX-505	Validity Expert Report of Leonard J. Chyall	UU	U.S. Patent 9,024,068 B2	Exhibit UU to the Validity Expert Report of Leonard J. Chyall		PP

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DTX-506	Validity Expert Report of Leonard J. Chyall	VV	U.S. Patent 9,718,846 B1	Exhibit VV to the Validity Expert Report of Leonard J. Chyall		PP
DTX-507	Validity Expert Report of Leonard J. Chyall	WW	U.S. Patent 10,087,193 B2	Exhibit WW to the Validity Expert Report of Leonard J. Chyall		PP
DTX-508	Validity Expert Report of Leonard J. Chyall	XX	WO 2015/149727 A1	Exhibit XX to the Validity Expert Report of Leonard J. Chyall		PP
DTX-509	Validity Expert Report of Leonard J. Chyall	ZZ	Determination of Melting Point-Mixed Melting Points, I,34, in VOGEL'S TEXTBOOK OF PRACTICAL ORGANIC CHEMISTRY, at 223 (1978)	Exhibit ZZ to the Validity Expert Report of Leonard J. Chyall		PP
DTX-510	Invalidity expert report of Piotr Karpinski	A	Curriculum vitae of Piotr Karpinski	Exhibit A to the Invalidity expert report of Piotr Karpinski		

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DTX-511	Invalidity expert report of Piotr Karpinski	B	Expert report from Polycrystalline	Exhibit B to the Invalidity expert report of Piotr Karpinski		H, U
DTX-512	Invalidity expert report of Piotr Karpinski	C	List of Materials Cited by Piotr Karpinski	Excerpt from Exhibit C to the Invalidity expert report of Piotr Karpinski		
DTX-513	Reply expert report of Piotr Karpinski	A	Davey R.J. & Garside J., From molecules to crystallizers, Oxford University Press, at 1-5, 36-43 (2000)	Exhibit A to the Reply expert report of Piotr Karpinski		PP
DTX-514	Reply expert report of Piotr Karpinski	B	Franklin et al., Mechanics and Heat: A Text Book for Colleges and Technical Schools, p. 317 (1910)	Exhibit B to the Reply expert report of Piotr Karpinski		PP

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DTX-515	Reply expert report of Piotr Karpinski	C	S. Oka et al., Staurosporine, a Potent Platelet Aggregation Inhibitor from a Streptomyces Species, AGRIC. BIOL. CHEM. 50 (11), 1986	Exhibit C to the Reply expert report of Piotr Karpinski		PP
DTX-516	Reply expert report of Piotr Karpinski	D	Lian Yu, Amorphous pharmaceutical solids: preparation, characterization and stabilization, ADVANCED DRUG REVIEWS 48 (2001)	Exhibit D to the Reply expert report of Piotr Karpinski		PP
DTX-519	Validity Expert Report of Mark Levis	C	Curriculum vitae of Dr. Mark J. Lewis	Exhibit C to the Validity Expert Report of Mark Levis		
DTX-522	Validity Expert Report of Mark Levis	F	Materials reviewed and relied upon	Exhibit F to the Validity Expert Report of Mark Levis		

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DTX-527	Validity Expert Report of Mark Levis	K	Rüdiger Hehlmann et al., Management of CML-Blast Crisis, 29 BEST PRAC. & RES. CLINICAL HAEMATOLOGY 295, 300-01 (2016)	Exhibit K to the Validity Expert Report of Mark Levis		PP
DTX-528	Validity Expert Report of Mark Levis	L	Michael W.N. Deininger et al., The Molecular Biology of Chronic Myeloid Leukemia, 96 BLOOD 3343, Fig. 4 (2000)	Exhibit L to the Validity Expert Report of Mark Levis	Shah Validity Report Ex. II; Lindsley Dep. Ex. 22	PP
DTX-529	Validity Expert Report of Mark Levis	M	Markus Warmuth et al., The Src Family Kinase Hck Interacts with Bcr-Abl by a Kinase independent Mechanism and Phosphorylates the Grb2-binding Site of Bcr, 272 J. Biological Chemistry 33260 (1997)	Exhibit M to the Validity Expert Report of Mark Levis	Reply expert report of Craig Lindsley Ex. O; Validity Expert Report of Neil Shah Ex. VV; Murcko Responsive Report Ex. O; Lindsley Dep. Ex. 19	PP

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DTX-530	Validity Expert Report of Mark Levis	N	Brian J. Druker & Nicholas B. Lydon, Lessons Learned from the Development of an Abl Tyrosine Kinase Inhibitor for Chronic Myelogenous Leukemia, 105 J. CLINICAL INVESTIGATION 3 (2000)	Exhibit N to the Validity Expert Report of Mark Levis	Shah Validity Report Ex. XX; Thirman Reply Report Ex. D; Lindsley Dep. Ex. 21; Murcko Expert Report Ex. H	PP
DTX-531	Validity Expert Report of Mark Levis	O	Brian J. Druker et al., Effects of a Selective Inhibitor of the Abl Tyrosine Kinase on the Growth of Bcr-Abl Positive Cells, 2 NATURE MED. 561, 562 (1996)	Exhibit O to the Validity Expert Report of Mark Levis	Thirman Reply Report Ex. C; Shah Validity Report Ex. YY; Murcko Responsive Report Ex. Q	PP
DTX-532	Validity Expert Report of Mark Levis	P	Philipp le Coutre et al., In Vivo Eradication of Human BCR/ABL-Positive Leukemia Cells with an ABL Kinase Inhibitor, 91 J. Nat'l Cancer Inst., 163, 165-66 (1999)	Exhibit P to the Validity Expert Report of Mark Levis		PP
DTX-533	Validity Expert Report of Mark Levis	Q	Brian J. Druker et al., Efficacy and Safety of a Specific Inhibitor of the Bcr-Abl Tyrosine Kinase in Chronic Myeloid Leukemia, 344 NEW ENG. J. MED. 1031 (2001)	Exhibit Q to the Validity Expert Report of Mark Levis	Shah Validity Report Ex. SSS; Shah Reply Report Ex. EE; Lindsley Dep. Ex. 28; Murcko Responsive Report Ex. J; Thirman Reply Report Ex. E	PP

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DTX-534	Validity Expert Report of Mark Levis	R	Brian J. Druker et al., Chronic Myelogenous Leukemia, 1 Hematology 111, 112 (2002)	Exhibit R to the Validity Expert Report of Mark Levis	Lindsley Dep. Ex. 31; Murcko Responsive Report Ex. P	PP
DTX-535	Validity Expert Report of Mark Levis	S	Lydia Roy et al., Survival Advantage from Imatinib Compared with the Combination Interferon- α Plus Cytarabine in Chronic-Phase Chronic Myelogenous Leukemia: Historical Comparison Between Two Phase 3 Trials, 108 Blood 1478, 1479 (2006)	Exhibit S to the Validity Expert Report of Mark Levis		PP
DTX-536	Validity Expert Report of Mark Levis	T	Ctr. for Drug Evaluation & Research, Application Number NDA 21-335, Gleevec Final Printed Labeling 6 (2001)	Exhibit T to the Validity Expert Report of Mark Levis	Murcko Responsive Report Ex. JJ	
DTX-538	Validity Expert Report of Mark Levis	V	Harold Boxenbaum & Clifford DiLea, First-Time-in-Human Dose Selection: Allometric Thoughts and Perspectives, 35 J. Clinical Pharmacology. 957, 958 (1995)	Exhibit V to the Validity Expert Report of Mark Levis		PP
DTX-539	Validity Expert Report of Mark Levis	W	Bruno G. Reigner & Karen Smith Blesch, Estimating the Starting Dose for Entry into Humans: Principles and Practice, 57 Eur. J. Clinical Pharmacology 835, 836-38 (2002)	Exhibit W to the Validity Expert Report of Mark Levis		PP

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DTX-540	Validity Expert Report of Mark Levis	X	Eiichi Fuse, et al., Prediction of the Maximal Tolerated Dose (MTD) and Therapeutic Effect of Anticancer Drugs in Humans: Integration of Pharmacokinetics with Pharmacodynamics and Toxicodynamics, 21 Cancer Treatment Reviews 133, 133-34 (1995)	Exhibit X to the Validity Expert Report of Mark Levis		PP
DTX-541	Validity Expert Report of Mark Levis	Y	James W. Paxton, The Allometric Approach for Interspecies Scaling of Pharmacokinetics and Toxicity of Anti-Cancer Drugs, 22 Clinical & Experimental Pharmacology & Physiology 851, 853 (1995)	Exhibit Y to the Validity Expert Report of Mark Levis		PP
DTX-542	Validity Expert Report of Mark Levis	Z	February 2004 IND 68268 Pre-IND Meeting Briefing Package	PFE-BOS01441751 - 823		
DTX-543	Validity Expert Report of Mark Levis	AA	Bosutinib 2011 Investigator's Brochure	PFE-BOS00302596 - 770		
DTX-544	Validity Expert Report of Mark Levis	BB	Adil I. Daud et al., Phase I Study of Bosutinib, a Src/Abl Tyrosine Kinase Inhibitor, Administered to Patients with Advanced Solid Tumors, 18 Clinical Cancer Res. 1092, 1092 (2012)	Exhibit BB to the Validity Expert Report of Mark Levis		PP

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DTX-545	Validity Expert Report of Mark Levis	CC	Jorge E. Cortes et al., Safety and Efficacy of Bosutinib (SKI-606) in Chronic Phase Philadelphia Chromosome–Positive Chronic Myeloid Leukemia Patients With Resistance or Intolerance to Imatinib, 118 BLOOD 4567 (2011)	Exhibit CC to the Validity Expert Report of Mark Levis	Shah Infringement Report Ex. FF; Shah Validity Report Ex. GGGG	PP
DTX-546	Validity Expert Report of Mark Levis	DD	Naoto Takahashi et al., Long-term Treatment with Bosutinib in a Phase 1/2 Study in Japanese Chronic Myeloid Leukemia Patients Resistant/Intolerant to Prior Tyrosine Kinase Inhibitor Treatment, 106 Int'l J. Hematology 398 (2017)	Exhibit DD to the Validity Expert Report of Mark Levis		PP
DTX-547	Validity Expert Report of Mark Levis	EE	Jorge E. Cortes et al., Bosutinib Versus Imatinib for Newly Diagnosed Chronic Myeloid Leukemia: Results from the Randomized BFORE Trial, 36 J. Clinical Oncology 231 (2017)	Exhibit EE to the Validity Expert Report of Mark Levis		PP
DTX-549	Validity Expert Report of Mark Levis	GG	U.S. Dept. of Health & Human Services, Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0 (2017)	Exhibit GG to the Validity Expert Report of Mark Levis		PP
DTX-550	Validity Expert Report of Mark Levis	HH	National Cancer Institute Cancer Evaluation Program, Common Toxicity Criteria, Version 2.0 (1999)	Exhibit HH to the Validity Expert Report of Mark Levis		PP

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DTX-554	Responsive Expert Report of Mark A. Murcko	C	Curriculum vitae of Dr. Mark A. Murcko	Exhibit C to the Responsive Expert Report of Mark A. Murcko		
DTX-555	Responsive Expert Report of Mark A. Murcko	D	Nicolas J. Donato et al., Use of c-Src Inhibitors Alone or in Combination with STI571 for the Treatment of Leukemia, WO 03/013540 (Feb. 20, 2003)	Exhibit D to the Responsive Expert Report of Mark A. Murcko	Lindsley Reply Report Ex. D	PP
DTX-558	Responsive Expert Report of Mark A. Murcko	G	List of materials relied upon	Exhibit G to the Responsive Expert Report of Mark A. Murcko		
DTX-560	Responsive Expert Report of Mark A. Murcko	I	Brian J. Druker et al., Activity of a Specific Inhibitor of the BCR-ABL Tyrosine Kinase in the Blast Crisis of Chronic Myeloid Leukemia and Acute Lymphoblastic Leukemia with the Philadelphia Chromosome, 344 NEW ENG. J. MED. 1038 (2001)	Exhibit I to the Responsive Expert Report of Mark A. Murcko	Shah Validity Report Ex. TTT; Lindsley Dep. Ex. 30; Thirman Reply Report Ex. F	PP

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DTX-564	Responsive Expert Report of Mark A. Murcko	M	Yi Liu et al., Structural Basis for Selective Inhibition of Src Family Kinases by PP1, 6 CHEMISTRY & BIOLOGY 671, 675 (1999)	Exhibit M to the Responsive Expert Report of Mark A. Murcko	Shah Validity Report Ex. TT	PP
DTX-565	Responsive Expert Report of Mark A. Murcko	N	Susanne Danhauser-Riedl et al., Activation of Src Kinases p53/56lyn and p59hck by p210bcr/abl in Myeloid Cells, 56 CANCER RES. 3589 (1996)	Exhibit N to the Responsive Expert Report of Mark A. Murcko		PP
DTX-569	Responsive Expert Report of Mark A. Murcko	R	Jeffrey H. Hanke et al., Discovery of a Novel, Potent, and Src Family-selective Tyrosine Kinase Inhibitor: Study of Lck- and FynT-Dependent T Cell Activation, 271 J. BIOLOGICAL CHEMISTRY 695, 697-98 (1996)	Exhibit R to the Responsive Expert Report of Mark A. Murcko	Shah Validity Report Ex. CCC	PP

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DTX-571	Responsive Expert Report of Mark A. Murcko	T	Markus Warmuth et al., Dual-Specific Src and Abl Kinase Inhibitors, PP1 and CGP76030, Inhibit Growth and Survival of Cells Expressing Imatinib Mesylate-Resistant Bcr-Abl Kinases, 15 BLOOD 664 (2003)	Exhibit T to the Responsive Expert Report of Mark A. Murcko	Lindsley Dep. Ex. 34; Lindsley Reply Report Ex. P; Shah Validity Report Ex. FFF	PP
DTX-572	Responsive Expert Report of Mark A. Murcko	U	Ramadevi Nimmanapalli et al., Molecular Characterization and Sensitivity of STI-571 (Imatinib Mesylate, Gleevec)-resistant, Bcr-Abl-positive, Human Acute Leukemia Cells to SRC Kinase Inhibitor PD180970 and 17-Allylamino-17-demethoxygeldanamycin, 62 Cancer Res. 5761, 5761 (2002)	Exhibit U to the Responsive Expert Report of Mark A. Murcko	Shah Validity Report Ex. KKK; Lindsley Reply Report Ex. I; Lindsley Dep. Ex. 35	PP
DTX-573	Responsive Expert Report of Mark A. Murcko	V	Bhushan Nagar et al., Crystal Structures of the Kinase Domain of c-Abl in Complex with the Small Molecule Inhibitors PD173955 and Imatinib (STI-571), 62 CANCER RES. 4236, 4236 (2002)	Exhibit V to the Responsive Expert Report of Mark A. Murcko	Shah Validity Report Ex. AAA	PP

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DTX-575	Responsive Expert Report of Mark A. Murcko	X	U.S. Patent 8,119,649 B2	Exhibit X to the Responsive Expert Report of Mark A. Murcko		PP
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DTX-577	Responsive Expert Report of Mark A. Murcko	Z	Fahad A. Al-Obeidi & Kit S. Lam, Development of Inhibitors for Protein Tyrosine Kinases, 19 Oncogene 5690, 5692 (2000)	Exhibit Z to the Responsive Expert Report of Mark A. Murcko		PP
DTX-578	Responsive Expert Report of Mark A. Murcko	AA	Thomas Schindler et al., Structural Mechanism for STI-571 Inhibition of Abelson Tyrosine Kinase, 289 Science 1938, 1939 (2000)	Exhibit AA to the Responsive Expert Report of Mark A. Murcko		PP

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DTX-581	Responsive Expert Report of Mark A. Murcko	DD	Uwe Trinks et al., Dianilinophthalimides: Potent and Selective, ATP-Competitive Inhibitors of the EGF-Receptor Protein Tyrosine Kinase, 37 J. Med. Chemistry 1015, 1017, Table 2 (1994)	Exhibit DD to the Responsive Expert Report of Mark A. Murcko		PP
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DTX-583	Responsive Expert Report of Mark A. Murcko	FF	Martin Missbach et al., Substituted 5,7-Diphenyl-pyrrolo[2,3d]pyrimidines: Potent Inhibitors of the Tyrosine Kinase c-Src, 10 Bioorganic & Med. Chemistry Letters 945, 947, Table 1 (2000)	Exhibit FF to the Responsive Expert Report of Mark A. Murcko		PP

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DTX-585	Responsive Expert Report of Mark A. Murcko	HH	Leo Widler et al., 7-Alkyl- and 7-Cycloalkyl-5-aryl-pyrrolo[2,3-d]pyrimidines--Potent Inhibitors of the Tyrosine Kinase c-Src, 11 Biorganic & Med. Chemistry Letters 849, 851-52, Tables 1 and 2 (2001)	Exhibit HH to the Responsive Expert Report of Mark A. Murcko		PP
DTX-586	Responsive Expert Report of Mark A. Murcko	II	Michael J. Mauro & Brian J. Druker, STI571: Targeting BCR-ABL as Therapy for CML, 6 ONCOLOGIST 233 (2001)	Exhibit II to the Responsive Expert Report of Mark A. Murcko	Shah Validity Report Ex. UUU; Lindsley Dep. Ex. 39	PP
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DTX-593	Responsive Expert Report of Berhardt L. Trout	C	Curriculum vitae of Dr. Bernhardt L. Trout	Exhibit C to the Responsive Expert Report of Berhardt L. Trout		
DTX-596	Responsive Expert Report of Berhardt L. Trout	F	List of materials cited and listed in report	Exhibit F to the Responsive Expert Report of Berhardt L. Trout		
DTX-597	Responsive Expert Report of Berhardt L. Trout	G	Gareth Thomas ed., Ch. 3 An Introduction to Drug Discovery, in Fundamentals of Medicinal Chemistry 57, 57-58 (2003)	Exhibit G to the Responsive Expert Report of Berhardt L. Trout		PP
DTX-598	Responsive Expert Report of Berhardt L. Trout	H	Gareth Thomas ed., Ch. 11: Drug Development and Production, in Fundamentals of Medicinal Chemistry 223, 223-24 (2003)	Exhibit H to the Responsive Expert Report of Berhardt L. Trout		PP

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DTX-600	Responsive Expert Report of Berhardt L. Trout	J	Lester A. Mitscher, Ch. 1: Drug Design and Discovery: An Overview, in Textbook of Drug Design and Discovery 1, 9-11 (Povl Krogsgaard-Larsen et al. eds., 3d ed. 2002)	Exhibit J to the Responsive Expert Report of Berhardt L. Trout		PP
DTX-601	Responsive Expert Report of Berhardt L. Trout	K	Howard Y. Ando & Galen W. Radebaugh, Ch. 38: Preformulation, in Remington: The Science and Practice of Pharmacy 700, 700-01 (Alfonso R. Gennaro et al. eds., 20th ed. 2000)	Exhibit K to the Responsive Expert Report of Berhardt L. Trout		PP
DTX-602	Responsive Expert Report of Berhardt L. Trout	L	Maria L. Webb, Ch. 10: Research, in Remington: The Science and Practice of Pharmacy 81, 87-88 (Alfonso R. Gennaro et al. eds., 20th ed. 2000)	Exhibit L to the Responsive Expert Report of Berhardt L. Trout		PP
DTX-603	Responsive Expert Report of Berhardt L. Trout	M	Garnet E. Peck, Ch. 36: Separation, in Remington: The Science and Practice of Pharmacy 669, 669 (Alfonso R. Gennaro et al. eds., 20th ed. 2000)	Exhibit M to the Responsive Expert Report of Berhardt L. Trout		PP

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DTX-604	Responsive Expert Report of Berhardt L. Trout	N	ICH, Guideline for Industry: Impurities in New Drug Substances Q3A, 2-3, 5 (Jan. 1996)	Exhibit N to the Responsive Expert Report of Berhardt L. Trout		PP
DTX-605	Responsive Expert Report of Berhardt L. Trout	O	U.S. Pharmacopeial Convention, Inc., 1074 Excipient Biological Safety Evaluation Guidelines, in U.S. Pharmacopeia and National Formulary (USP 25–NF 20) 2145, 2146 (2002)	Exhibit O to the Responsive Expert Report of Berhardt L. Trout		PP
DTX-606	Responsive Expert Report of Berhardt L. Trout	P	Arthur H. Kibbe ed., Preface, in Handbook of Pharmaceutical Excipients xv, xv (3d ed. 2000)	Exhibit P to the Responsive Expert Report of Berhardt L. Trout		PP
DTX-607	Responsive Expert Report of Berhardt L. Trout	Q	U.S. Pharmacopeial Convention, Inc., 1078 Good Manufacturing Processes for Bulk Pharmaceutical Excipients, in U.S. Pharmacopeia and National Formulary (USP 25–NF 20) 2148, 2148-49 (2002)	Exhibit Q to the Responsive Expert Report of Berhardt L. Trout		PP

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DTX-608	Responsive Expert Report of Berhardt L. Trout	R	U.S. Pharmacopeial Convention, Inc., Preface, in U.S. Pharmacopeia and National Formulary (USP 25–NF 20) xlv, xlv (2002)	Exhibit R to the Responsive Expert Report of Berhardt L. Trout		PP
DTX-609	Responsive Expert Report of Berhardt L. Trout	S	U.S. Pharmacopeial Convention, Inc., Polysorbate 80, Official Monographs, in U.S. Pharmacopeia and National Formulary (USP 25–NF 20) 2603, 2603 (2002)	Exhibit S to the Responsive Expert Report of Berhardt L. Trout		PP
DTX-610	Responsive Expert Report of Berhardt L. Trout	T	Axel Wolff et al., Office of Laboratory Animal Welfare Frequently Asked Questions About the Public Health Service Policy on Humane Care and Use of Laboratory Animals, 32 Lab Animal 33 (2003)	Exhibit T to the Responsive Expert Report of Berhardt L. Trout	Lindsley Reply Report Ex. S	PP
DTX-611	Responsive Expert Report of Berhardt L. Trout	U	Sigma-Aldrich, Polyoxyethylenesorbitan Monooleate (Tween 80), Products for Life Science Research, 2000-2001 at 361, 972	Exhibit U to the Responsive Expert Report of Berhardt L. Trout		PP
DTX-612	Responsive Expert Report of Berhardt L. Trout	V	Sigma-Aldrich, General Information, Products for Life Science Research, 2000-2001 at 2	Exhibit V to the Responsive Expert Report of Berhardt L. Trout		PP

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DTX-614	Responsive Expert Report of Berhardt L. Trout	X	Sigma-Aldrich, D(+)-Glucose (Dextrose), Products for Life Science Research, 2000-2001 at 241	Exhibit X to the Responsive Expert Report of Berhardt L. Trout		PP
DTX-615	Responsive Expert Report of Berhardt L. Trout	Y	TNJ Chemical, Pharmaceutical Grade Dextrose (Anhydrous & Monohydrate), www.tnjchem.com/pharmaceutical-grade-dextrose-anhydrous-monohydrate-at-bestprice_p1442.html (last visited May 9, 2019)	Exhibit Y to the Responsive Expert Report of Berhardt L. Trout		PP
DTX-616	Responsive Expert Report of Berhardt L. Trout	Z	U.S. Pharmacopeial Convention, Inc., Water, Official Monographs, in U.S. Pharmacopeia and National Formulary (USP 25–NF 20) 1809, 1809-10 (2002)	Exhibit Z to the Responsive Expert Report of Berhardt L. Trout		PP
DTX-617	Responsive Expert Report of Berhardt L. Trout	AA	Kenneth E. Avis & John W. Levchuck, Ch. 41 Parenteral Preparations, in Remington: The Science and Practice of Pharmacy 780, 783-84 (Alfonso R. Gennaro et al. eds., 20th ed. 2000)	Exhibit AA to the Responsive Expert Report of Berhardt L. Trout		PP

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DTX-618	Responsive Expert Report of Berhardt L. Trout	BB	J.G. Nairn, Ch. 39: Solutions, Emulsions, Suspensions, and Extracts, in Remington: The Science and Practice of Pharmacy 721, 722 (Alfonso R. Gennaro et al. eds., 20th ed. 2000)	Exhibit BB to the Responsive Expert Report of Berhardt L. Trout		PP
DTX-619	Responsive Expert Report of Berhardt L. Trout	CC	U.S. Food & Drug Admin., Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances, 65 Fed. Reg. 83,042, §§ 3.2–3.3 (Dec. 29, 2000)	Exhibit CC to the Responsive Expert Report of Berhardt L. Trout		PP
DTX-620	Responsive Expert Report of Berhardt L. Trout	DD	Ctr. for Drug Evaluation & Research, Guidance for Industry: INDs for Phase 2 and Phase 3 Studies – Chemistry, Manufacturing, and Controls Information §§ III.A.4, B.3-4, IV.A.4, B.3-4 (2003)	Exhibit DD to the Responsive Expert Report of Berhardt L. Trout		PP
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DTX-622	Responsive Expert Report of Berhardt L. Trout	FF	Arthur H. Kibbe, ed, Dextrose, in Handbook of Pharmaceutical Excipients 175, 176 (3rd ed. 2000)	Exhibit FF to the Responsive Expert Report of Berhardt L. Trout		PP

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DTX-624	Responsive Expert Report of Berhardt L. Trout	HH	A.M. Katti & P. Jagland, Development and Optimization of Industrial Scale Chromatography for Use in Manufacturing, 26 Analisis Mag. 38, 45-46 (1998)	Exhibit HH to the Responsive Expert Report of Berhardt L. Trout		PP
DTX-625	Responsive Expert Report of Berhardt L. Trout	II	Steven A. Hardinger, A Simple Demonstration of the Effect of Impurities on Melting Point, 72 J. Chemical Educ. 250, 250 (1995)	Exhibit II to the Responsive Expert Report of Berhardt L. Trout		PP
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DTX-628	Responsive Expert Report of Berhardt L. Trout	LL	Irwin Reich et al., Ch. 18: Tonicity, Osmoticity, Osmolality, and Osmolarity, in Remington: The Science and Practice of Pharmacy 246, 247 (Alfonso R. Gennaro et al. eds., 20th ed. 2000)	Exhibit LL to the Responsive Expert Report of Berhardt L. Trout		PP
DTX-630	Reply Expert Report of Michael J. Thirman	A	List of Materials Considered	Exhibit A to the Reply Expert Report of Michael J. Thirman		
DTX-631	Reply Expert Report of Michael J. Thirman	B	Curriculum vitae of Dr. Michael J. Thirman	Exhibit B to the Reply Expert Report of Michael J. Thirman		
DTX-638	Reply Expert Report of Michael J. Thirman	I	Hantel et al., Imatinib is still recommended for frontline therapy for CML, Blood Advances Volume 2, Number 24: 3648-3652 (2018)	Exhibit I to the Reply Expert Report of Michael J. Thirman		PP
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DTX-648	Invalidity expert report of Piotr Karpinski	C	Chong Hui Gu, C., Victor G. Young, & David J.W. Grant, Polymorph Screening: Influence of Solvents on the Rate of Solvent-Mediated Polymorphic Transformation. J. Pharm. Sci., 90: 1878-1890 (2001)	Excerpt from Exhibit C to the Invalidity expert report of Piotr Karpinski		
DTX-649	Invalidity expert report of Piotr Karpinski	C	ICH Harmonised Tripartite Guideline, Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances Q6A, Public_Web_Site/ICH_Products/Guidelines/Quality/Q6A/Step4/Q6Astep4.pdf (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, October 6, 1999)	Excerpt from Exhibit C to the Invalidity expert report of Piotr Karpinski		
DTX-650	Invalidity expert report of Piotr Karpinski	C	Stephen Byrn, Ralph Pfeiffer, Michael Ganey, Charles Hoiberg, & Guirag Poochikian, Pharmaceutical Solids: A Strategic Approach to Regulatory Considerations, Pharmaceutical Research, Vol. 12, No. 7 (1995)	Excerpt from Exhibit C to the Invalidity expert report of Piotr Karpinski		

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DTX-651	Invalidity expert report of Piotr Karpinski	C	Sherry L. Morissette et al., High-throughput crystallization: polymorphs, salts, co-crystals and solvates of pharmaceutical solids, Advanced Drug Delivery Reviews, 56(3):275-300 (2004)	Excerpt from Exhibit C to the Invalidity expert report of Piotr Karpinski		
DTX-652	Invalidity expert report of Piotr Karpinski	C	Henry G. Brittain, Polymorphism in Pharmaceutical Solids, in 95 Drugs and the Pharmaceutical Sciences, 41 (1999)	Excerpt from Exhibit C to the Invalidity expert report of Piotr Karpinski		
DTX-653	Invalidity expert report of Piotr Karpinski	C	Német Z, Sajó I, Demeter A. (2010) Rietveld refinement in the routine quantitative analysis of famotidine polymorphs. J. Pharm. and Biomed. Analysis, 51, 572-576	Excerpt from Exhibit C to the Invalidity expert report of Piotr Karpinski		
DTX-654	Invalidity expert report of Piotr Karpinski	C	Silva R P, M F S Ambrósio, E K Epprecht, R R Avillez, C A Achete , A Kuznetsov, L C Visentin (2016) Validation of the method of quantitative phase analysis by X-ray diffraction in API: case of Tibolone J. Phys.: Conf. Ser. 733 012030	Excerpt from Exhibit C to the Invalidity expert report of Piotr Karpinski		

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DTX-655	Invalidity expert report of Piotr Karpinski	C	Eszter Tieger, "Investigation of the pharmaceutical applicability of solvates: screening, characterization, crystallization" PhD Thesis 2017, Budapest University of Technology and Economics, Faculty of Chemical Technology and Biotechnology, https://repozitorium.omikk.bme.hu/bitstream/handle/10890/5428/ertekezes.pdf?	Excerpt from Exhibit C to the Invalidity expert report of Piotr Karpinski		
DTX-656	Deposition of Brian Druker	5	2002-10-18 Email from Frank Boschelli	PFE-BOS01566859 - 860		
DTX-657	Deposition of Brian Druker	5	2002-11-04 Email from Heidi Henning	Excerpt from Exhibit 5 to the Deposition of Brian Druker		

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DTX-658	Deposition of Brian Druker	5	2002-11-04 Email from Sarah to Shelly Ziegler	Excerpt from Exhibit 5 to the Deposition of Brian Druker		
DTX-659	Deposition of Brian Druker	5	2003-01-07 Email from Janet Lucas	Excerpt from Exhibit 5 to the Deposition of Brian Druker		
DTX-660	Deposition of Brian Druker	5	2003-01-07 Email from Sarah Anderson	Excerpt from Exhibit 5 to the Deposition of Brian Druker		

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DTX-661	Deposition of Brian Druker	5	2003-01-07 Email from Sarah Anderson	Excerpt from Exhibit 5 to the Deposition of Brian Druker		
DTX-662	Deposition of Brian Druker	5	2003-01-15 Email from Sarah Anderson	Excerpt from Exhibit 5 to the Deposition of Brian Druker		
DTX-663	Deposition of Brian Druker	5	2003-01-23 Email from Sarah Anderson	Excerpt from Exhibit 5 to the Deposition of Brian Druker		

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DTX-664	Deposition of Brian Druker	5	2003-01-28 Email from Jeff Barnhardt	Excerpt from Exhibit 5 to the Deposition of Brian Druker		
DTX-665	Deposition of Brian Druker	5	2003-01-30 Email from Sarah Anderson	Excerpt from Exhibit 5 to the Deposition of Brian Druker		
DTX-666	Deposition of Brian Druker	5	2003-02-10 Email from Sarah Anderson	Excerpt from Exhibit 5 to the Deposition of Brian Druker		

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DTX-667	Deposition of Brian Druker	5	2003-02-15 Email from Sarah Anderson	Excerpt from Exhibit 5 to the Deposition of Brian Druker		
DTX-668	Deposition of Brian Druker	5	2003-03-12 Email from Sarah Anderson	Excerpt from Exhibit 5 to the Deposition of Brian Druker		
DTX-669	Deposition of Brian Druker	5	2003-04-16 Email from Sarah Anderson	Excerpt from Exhibit 5 to the Deposition of Brian Druker		

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DTX-670	Deposition of Brian Druker	5	2014-07-15 Email from Sarah Anderson to Brian Druker	Excerpt from Exhibit 5 to the Deposition of Brian Druker		

EXHIBIT 12

EXHIBIT 12

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH LLC, WYETH)	
PHARMACEUTICALS LLC, PF PRISM)	
C.V., PBG PUERTO RICO LLC and)	
PF PRISM IMB B.V.)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 16-1305 (RGA)
)	CONSOLIDATED
SUN PHARMACEUTICAL INDUSTRIES)	
LIMITED and SUN PHARMACEUTICAL)	
INDUSTRIES, INC.,)	
)	
Defendants.)	
)	
)	

JOINT TRIAL EXHIBIT LIST

EXHIBIT 12

Joint Exhibit No.	Document Title / Description	Date	Bates Nos.
JTX - 001	U.S. Patent Number 7,417,148	8/26/2008	PFZFH0001198 - 208
JTX - 002	U.S. Patent Number 7,767,678	8/3/2010	PFZFH0001220 - 39
JTX - 003	U.S. Patent Number 7,919,625	4/5/2011	PFZFH0001209 - 19
JTX - 004	'148 patent file history certificate		PFZFH0000001
JTX - 005	File History 10980097		PFZFH0000002 -473
JTX - 006	'678 patent file history certificate		PFZFH0000474
JTX - 007	File History 11478216 ('678 patent)		PFZFH0000475 - 1020
JTX - 008	'625 patent file history certificate		PFZFH0001021
JTX - 009	File History 12139834 ('625 patent)		PFZFH0001022 - 197
JTX - 010	Label for Pfizer's Bosulif - Latest Version (August 2019)		
JTX - 011	INTENTIONALLY LEFT BLANK		
JTX - 012	Provisional Application No. 60/517,819	11/6/2003	PFZFH0001249 - 99
JTX - 013	Provisional Application No. 60/696,381	9/26/2005	PFZFH0001300 - 41
JTX - 014	Terminal Disclaimer '148 Patent		PFZFH0001240 - 48
JTX - 015	Label for Sun's Bosutinib Tablets - Latest Version (December 2018)	12/00/2018	SUN-BOS0089353 - 78